



Experimental Pathology Laboratories, Inc.

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Vinyl Chloride

**PATHOLOGY QUALITY ASSESSMENT  
REVIEW AND PWG COORDINATOR'S REPORT  
FOR  
LIFETIME CARCINOGENICITY STUDY  
OF VINYL CHLORIDE  
IN SPRAGUE-DAWLEY RATS**

**CONDUCTED AT**

**THE CANCER RESEARCH CENTER, EUROPEAN RAMAZZINI FOUNDATION  
FOR ONCOLOGY AND ENVIRONMENTAL SCIENCES, BOLOGNA, ITALY**

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## Table of Contents

INTRODUCTION.....	1
EXPERIMENTAL DESIGN AND METHODS.....	2
RESULTS .....	3
Quality Assessment Review .....	3
Pathology Working Group Review .....	4
CONFLICT OF INTEREST STATEMENT .....	7
SIGNATURE PAGE .....	8
APPENDIX A	
Slide Review Work Sheets - Males .....	A-1 – A-25
APPENDIX B	
Slide Review Work Sheets - Females .....	B-1 – B-32
APPENDIX C	
PWG Participants Curricula Vitae .....	C-1 – C-91



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Experimental Pathology Laboratories, Inc.

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**NARRATIVE**

Vinyl Chloride

**PATHOLOGY QUALITY ASSESSMENT REVIEW AND  
PATHOLOGY WORKING GROUP (PWG) COORDINATOR'S REPORT  
FOR  
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Quality Assessment Review: March 14-17, 2011

Date of the Pathology Working Group: April 4 – 8, 2011

PWG Coordinator: Robert R. Maronpot, DVM, MPH

Quality Assessment Pathologist: Peter C. Mann, DVM (EPL)

Study Diagnoses: Ramazzini Institute

PWG Participants:

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PWG Observers:

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Fiorella Belpoggi (Ramazzini Institute)

Morando Soffritti, MD (Ramazzini Institute)

Eva Tibaldi (Ramazzini Institute)

Laura Falcioni (Ramazzini Institute)

## **INTRODUCTION**

This report by Experimental Pathology Laboratories, Inc. (EPL<sup>®</sup>) presents the results of the Quality Assessment Review and the Pathology Working Group (PWG) which reviewed glass slides subsequent to the Quality Assessment Review of the Vinyl Chloride (VC) study. The VC study was conducted by the Ramazzini Institute by inhalation administration. The study started in 1974 and involved 318 rats.

**EXPERIMENTAL DESIGN AND METHODS**

One day old Sprague-Dawley rats were exposed to vinyl chloride by inhalation for 4 hours per day, 5 days per week, for a total of 5 weeks and then held without further treatment for their lifetime. The numbers of animals used and their allocation to dose groups are shown in Table 1.

Table 1 – Study Design for Bioassay on Vinyl Chloride Administered in Drinking Water to Male and Female Sprague-Dawley Rats

Dose Group	No. Rat and Sex
10000 ppm	25 Males & 21 Females
6000 ppm	18 Males & 25 Females
0 ppm	109 Males & 120 Females

Results of vinyl chloride study findings have been published previously by the Ramazzini Institute. The publication citations are as follows:

- Maltoni, C. (1977). Recent Findings on the Carcinogenicity of Chlorinated Olefins. *Environmental Health Perspectives* 21: 1-5.
- Maltoni, C. and Lefemine, G. (1975). Carcinogenicity Bioassays of Vinyl Chloride: Current Results. In: *Toxicity of Vinyl Chloride-Polyvinyl Chloride*. I.J. Selikoff and E.C. Hammond, Eds. New York Academy of Sciences pp: 195-218.
- Maltoni, C. and Lefemine, G. (1974). Carcinogenicity Bioassays of Vinyl Chloride. I. Research Plan and Early Results. *Environmental Research* 7: 387-405.
- Maltoni, C., Lefemine, G., Chieco, P. and Carretti, D. (1974). Vinyl Chloride Carcinogenesis: Current Results and Perspectives. *Med. Lavoro* 65: 421-444.

The peer review consisted of analysis of the Ramazzini Institute data and Quality Assessment (QA) of selected histopathology slides for the chronic lifetime study of vinyl chloride in Sprague-Dawley rats. The EPA request was to conduct liver sections for hyperplastic and neoplastic changes from all male and female rats in all groups.

All slides with differences of opinion relating to the presence or absence of preneoplastic and neoplastic lesions in the liver between the study and reviewing pathologist were identified for possible review by the Pathology Working Group.

Slide Review Work Sheets were used to document the results of the QA review. These work sheets list in animal number order tissues that were examined by the QA pathologist. In addition, these work sheets list the study pathologist's initial diagnosis for the tissues that were reviewed. The work sheets also record the QA pathologist's comments indicating agreement with the Ramazzini pathologist's diagnosis or a comment when a difference of opinion was noted.

The QA took place March 14-17, 2011 at the Ramazzini Institute. The number of slides examined during the QA review of the vinyl chloride study is listed in Table 2.

Table 2. Number of Slides Reviewed During the QA Review

	Males	Females
Group	Slide Count	Slide Count
10000 ppm	42	35
6000 ppm	34	48
0 ppm	117	129
TOTAL	193	212

The Pathology Working Group (PWG) Panel met on April 6 - 7, 2011 to examine 144 liver sections from 82 rats.

## RESULTS

All materials necessary for this review were readily available and well organized. All slides required to be examined by the QA pathologist were present. The histologic quality of the sections was considered to be very good with no deficiencies that interfered with the examination of the tissues present or the interpretation of histopathologic changes that were present.

### Quality Assessment Review

The quality assessment review resulted in several instances of changes in diagnostic nomenclature. Since the time this study was started in 1974, nomenclature for

hepatoproliferative lesions has changed. Ramazzini study pathologist's liver diagnoses of neoplastic nodules and nodular hyperplasia are either no longer used in the case of neoplastic nodule or only rarely used in the case of nodular hyperplasia. What was diagnosed as neoplastic nodule in past years is now consider either focus of cellular alteration or hepatocellular adenoma. Contemporary use of nodular hyperplasia is uncommon and such lesions are typically diagnosed as foci of cellular alteration or regenerative hyperplasia when there is evidence of antecedent or contemporary hepatotoxicity. Furthermore, liver tumors consisting of hepatocellular and cholangiocellular elements are now diagnosed as hepatocholangiomas or hepatocholangiocarcinomas based on changes in nomenclature occurring since this study was completed.

Slide Review Work Sheets used to document the results of the QA review are presented in Appendices A and B. These work sheets list in animal number order tissues that were examined by the QA pathologist from EPL. These work sheets list the initial diagnoses for the tissues which were reviewed and the QA pathologist's agreement or difference of opinion. The QA review consisted of examination of all livers for presence of preneoplastic and neoplastic lesions. When different preneoplastic and neoplastic lesions were present in the same liver, each was diagnosed during the QA review.

#### Pathology Working Group Review

The primary focus during the PWG review was to confirm the presence of preneoplastic and neoplastic liver lesions for rats where there was a difference in diagnosis between the study and QA pathologist. Many of the diagnostic differences between study and QA pathologists are a reflection of nomenclature changes that have become generally accepted since the present study was completed. Diagnostic criteria for proliferative liver lesions used during the QA and PWG reviews are provided in the following references:

Maronpot, R. R., Harada, T., Murthy, A. S., and Boorman, G. A. (1989). Documenting foci of hepatocellular alteration in two-year carcinogenicity studies: Current practices of the National Toxicology Program. *Toxicol Pathol* 17, 675-683.



Maronpot RR, Montgomery CA, Boorman GA, and McConnell EE, 1986. National Toxicology Program Nomenclature for Hepatoproliferative Lesions of Rats. *Tox. Path.* 14:263-273.

Harada T, Maronpot RR, Boorman GA, Morris RW, and Stitzel KA, 1990. Foci of Cellular Alteration in the Rat Liver: A Review. *Tox. Path.* 3:161-188.

Maronpot RR, 1990. Tumors of the Liver. In: *Atlas of Tumor Pathology of the Fischer Rat*. CRC Press, pp. 193-220.

Goodman DG, Maronpot RR, Newberne PM, Popp JA, and Squire RA, 1994. Proliferative and Selected Other Lesions in the Liver of Rats. In: *Guides for Toxicologic Pathology*. STP/ARP/AFIP, Washington, DC, pp. 1-24.

Thoolen, B., Maronpot, R. R., Harada, T., Nyska, A., Rousseaux, C., Nolte, T., Malarkey, D. E., Kaufmann, W., Kuttler, K., Deschl, U., Nakae, D., Gregson, R., Vinlove, M. P., Brix, A. E., Singh, B., Belpoggi, F., and Ward, J. M. (2010). Proliferative and nonproliferative lesions of the rat and mouse hepatobiliary system. *Toxicol Pathol* 38, 5S-81S.

The PWG Panel members independently reviewed 144 liver slides from 82 rats without knowledge of prior diagnoses by the QA and study pathologists. The liver lesions were complex often with multiple distinct and merging tumors in the same liver and in the same tissue section. The hepatocellular carcinomas tended to have a more glandular component than what is typically seen. When the glandular pattern was sufficiently prominent, the PWG Panel preferred a diagnosis of hepatocholangiocarcinoma, or more rarely hepatocholangioma. There were a number of borderline lesions, particularly involving the lesions ranging from eosinophilic focus of cellular alteration to adenoma to carcinoma. Basophilic foci were hard to identify since they were not tinctorially distinct. Consensus diagnoses for each type of lesion were recorded by the PWG Coordinator. The neoplastic lesions where there was agreement between the study and QA pathologist plus the consensus diagnoses from the PWG Panel review are presented in Tables 3 and 4 for males and females, respectively. Preneoplastic lesions including foci of cellular alteration and angiomatous hyperplasia are tabulated in Slide Review Worksheets in Appendices A and B. Aside from changes in nomenclature for liver lesions since completion of this study, there was good agreement between the QA and study pathologists. A high proportion of

livers reviewed by the PWG panel had foci of cellular alteration in addition to neoplastic lesions.

**Table 3: Liver Tumors in Male Sprague-Dawley Rats Exposed by Inhalation to Vinyl Chloride for a Total of Five Weeks (Four Hours Per Day, Five Days per Week)**

Liver Lesion	0 ppm N = 104	6000 ppm N = 18	10000 ppm N = 25
Hepatocellular Adenoma	0	2	3
Hepatocellular Carcinoma	0	8	11
Hepatocellular Adenoma and Carcinoma	0	0	1
Hepatocellular Adenoma or Carcinoma	0	10	13
Cholangioma	0	1	2
Cholangiocarcinoma	0	0	1
Cholangioma and Cholangiocarcinoma	0	0	1
Cholangioma or Cholangiocarcinoma	0	1	2
Hepatocholangioma	0	0	1
Hepatocholangiocarcinoma	0	3	5
Hemangioma	0	1	0
Hemangiosarcoma	0	4	4
Hemangioma or Hemangiosarcoma	0	5	4
Histiocytic Sarcoma	2	0	1
Liver Tumor-Bearing Animals	2	12	18


**Table 4: Liver Tumors in Female Sprague-Dawley Rats Exposed by Inhalation to Vinyl Chloride for a Total of Five Weeks (Four Hours Per Day, Five Days per Week)**

Liver Lesion	0 ppm N = 117	6000 ppm N = 25	10000 ppm N = 20
Hepatocellular Adenoma	0	5	5
Hepatocellular Carcinoma	0	7	9
Hepatocellular Adenoma and Carcinoma	0	3	1
Hepatocellular Adenoma or Carcinoma	0	9	13
Cholangioma	0	2	0
Cholangiocarcinoma	0	0	2
Hepatocholangioma	0	1	0
Hepatocholangiocarcinoma	0	3	5
Hemangioma	0	0	1
Hemangiosarcoma	0	7	7
Hemangioma or Hemangiosarcoma	0	7	8
Histiocytic Sarcoma	1	0	0
Liver Tumor-Bearing Animals	1	14	16



## CONFLICT OF INTEREST STATEMENT

This statement is to certify that the person listed below, employed by Experimental Pathology Laboratories, Inc., participated in the QA review and Pathology Working Group (PWG) from the Lifetime Carcinogenicity Study of Vinyl Chloride in Sprague-Dawley Rats conducted at the Cancer Research Center, European Ramazzini Foundation for Oncology and Environmental Sciences. He has not been involved in any aspect of the study for any organization other than NTP which conducted the study nor the generation and/or evaluation of materials or data which were reviewed prior to the receipt of materials from the study lab. Hence, his participation in the PWG poses no apparent or actual conflict of interest.

  
For \_\_\_\_\_ 8/10/11  
ROBERT R. MARONPOT, D.V.M., M.S., M.P.H. DATE  
Diplomate, ACVP, ABT  
PWG Coordinator

RRM:asc



Experimental Pathology Laboratories, Inc.

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**SIGNATURE PAGE**

## PATHOLOGY WORKING GROUP (PWG) PARTICIPANTS:



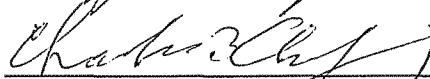
ROBERT R. MARONPOT, DVM, MS, MPH  
Diplomate, ACVP, ABT  
(PWG Coordinator)



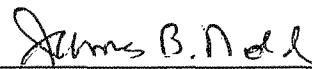
PETER GREAVES, MBChB, FRC Path



SABINE FRANCKE-CARROLL, DVM, PhD, FIATP



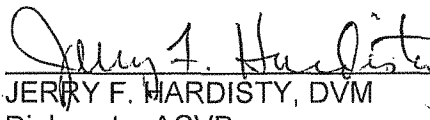
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Experimental Pathology Laboratories, Inc.

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**APPENDIX A**  
**SLIDE REVIEW WORK SHEETS**  
**MALE**

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1321		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1322		2	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1323		2	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1324		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
1325		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1326		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1327		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1328		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1329		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1330		1	LIVER - NORMAL	AGREE	NOT REVIEWED	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1331		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1332		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1333		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1334		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1335		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1336		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1337		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1338		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1339		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1340		1				



# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1340		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1341		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1342		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1343		0	LIVER - LYMPH LEUKAEMI, PRESENT	MISSING SLIDE	NOT REVIEWED	
1344		1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1345		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1346		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1347		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1348		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1349		1				

# SLIDE REVIEW WORKSHEET

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**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1349		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1350		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1351		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1352		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1353		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1354		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1355		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1356		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1357		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1358		1	LIVER - NORMAL	AGREE	NOT REVIEWED	

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**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1359		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1360		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1361		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1362		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1363		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1364		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1365		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1366		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1367		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1368		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
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**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1368		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1369		1	LIVER - CYST, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1370		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1371		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1372		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1373		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1374		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1375		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1376		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1377		1				

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
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TMT 5

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**CAS #**  
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**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1377		1	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
1378		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1379		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1380		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1381		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1382		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1383		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1384		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1385		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
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TMT 5

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**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1385		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1386		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1387		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1388		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1389		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1390		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1391		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1392		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1393		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1394		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
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TMT 5

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**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1394		1	LIVER - ANGIO HYP ATYP, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1395		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1396		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1397		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1398		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1399		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1400		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1401		2				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
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TMT 5

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**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1401		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1402		2	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
1403		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1404		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1405		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1406		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1407		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1408		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1409		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1410		1	LIVER - NORMAL	AGREE	NOT REVIEWED	



## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1411		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1412		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1413		3	LIVER - DIFFUSED HYPER, PRESENT	LIVER - HYPERPLASIA, MULTIFOCAL (-)	NOT REVIEWED	
			LIVER - FIBROSIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1414		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1415		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1416		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1417		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1418		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1419		1				

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1419		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	AGREE	NOT REVIEWED	
1420		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1421		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1422		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1423		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1424		2	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1425		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1426		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1427		2	LIVER - NORMAL	AGREE	NOT REVIEWED	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 5

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1428		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1429		2	LIVER - DIFFUSED HYPER, PRESENT	LIVER - HYPERPLASIA, MULTIFOCAL (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 3

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
63		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			<Inserted Finding>		LIVER: EOSIN FOCUS (-)	
64		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
65		1	LIVER - ANGIO HYP ATYP, PRESENT	LIVER - ANGIOMATOUS HYPERPLASIA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	LIVER: EOSIN FOCUS (-)	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 3

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
65	Cont'd	1	LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
66		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: EOSIN FOCUS (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
72		2	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCLR CARC (-)	
73		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
74		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 3

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
75		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
83		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
84		1	LIVER - NODULAR HYPERP, PRESENT	NO REMARKABLE LESION (-)	LIVER: EOSIN FOCUS (-)	
88		1	LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 3

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
89		4	LIVER - CHOLANGIOMA, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-) [PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
90		1	LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
94		2	LIVER - ANGIOMATOUS HY, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
95		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
96		2	LIVER - HAEMANGIOSARCO, PRESENT	LIVER - HAEMANGIOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCLR ADEN (-)	
100		2				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 3

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
100		2	LIVER - ANGIO HYP ATYP, PRESENT	AGREE	NOT REVIEWED	
			LIVER - BLRY DCT FIBRO, PRESENT	AGREE	NOT REVIEWED	
101		2	LIVER - ANGIOMATOUS HY, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-) {PWG}	LIVER: HEPATOCLR CARC (-)	



## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
16		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE[PWG]	NOT REVIEWED	
			LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOL (-)	
				LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
				LIVER - EOSINOPHILIC FOCUS (-)	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	New Finding - After[AGREE] {PWG}	NOT REVIEWED	
17		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
18		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
19		1	LIVER - NECROSIS, PRESENT	AGREE	LIVER: HEPATOCLR ADEN (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
19	Cont'd	1		LIVER - EOSINOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
20		1	LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
24		1	LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG]	LIVER: HEPATOCLR CARC (-)	
			<Inserted Finding>		LIVER: EOSIN FOCUS (-)	
25		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
26		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
27		3				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
27		3	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
28		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
29		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
29	Cont'd	3		LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
30		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
33		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
34		4	LIVER - CHOLANGIOMA, PRESENT	LIVER, BILE DUCT - CYST (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HISTIO SARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
35		2	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
36		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - HEPATOCELLULAR CARCINOMA (-)[VERY SMALL] {PWG}	AGREE WITH REVIEWING PATHOLOGIST	
37		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
38		1	LIVER - CHOLANGIOCARC, PRESENT	LIVER, BILE DUCT - CYST MULTILOCULAR (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
43		3	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
44		2	LIVER - CHOLANGIOMA, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-)[PWG]	AGREE WITH BOTH	
			LIVER - HAEMANGIOSARCO, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	NOT PRESENT IN SECTION (-)	
				LIVER - CHOLANGIOCARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	NOT PRESENT IN SECTION (-)	
51		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
52		3	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
53		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
54		2				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1M  
**Sex & Species** MALE SPRAGUE DAWLEY RAT

TMT 1

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
54		2	LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
58		1	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	NOT PRESENT IN SECTION (-)	



Experimental Pathology Laboratories, Inc.

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**APPENDIX B**  
**SLIDE REVIEW WORK SHEETS**  
**FEMALE**



# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1201		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1202		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1203		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1204		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1205		2	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1206		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1207		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1208		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
1209		2	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1209	Cont'd	2	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1210		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1211		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1212		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1213		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1214		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1215		1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1216		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1217		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1218		1				

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1218		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1219		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1220		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1221		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1222		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1223		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1224		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1224		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1225		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1226		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1227		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1228		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1229		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1230		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1231		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1232		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1233		2				

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1233		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1234		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1235		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1236		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1237		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1238		2	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1239		1	LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1240		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1241		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1241		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1242		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1243		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1244		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1245		2	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1246		1	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
1247		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1248		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1249		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1250		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1251		1	LIVER - BILIARY DCT HY, PRESENT	AGREE	NOT REVIEWED	
1252		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1253		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1254		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1255		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (=)	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1255	Cont'd	1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1256		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1257		1	LIVER - ANGIO HYP ATYP, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1258		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1259		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1260		1				



# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1260		1	LIVER - NECROSIS, PRESENT		NOT REVIEWED	
1261		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1262		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1263		3	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
				LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1264		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1265		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1266		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1267		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1268		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1269		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1270		2	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1271		1				

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1271		1	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1272		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1273		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1274		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1275		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1276		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
1277		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1277		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1278		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1279		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
				LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1280		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1281		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1282		0	LIVER - MISSING	AGREE	NOT REVIEWED	
1283		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1284		0	LIVER - MISSING	AGREE	NOT REVIEWED	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1285		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1286		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1287		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1288		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1289		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1290		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
1291		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1292		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1293		2				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1293		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1294		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1295		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
1296		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
1297		2	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
1298		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1299		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1299		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1300		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1301		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1302		0	LIVER - ANGIECTASIS, PRESENT	MISSING SLIDE	NOT REVIEWED	
1303		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1304		2	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1305		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1306		1	LIVER - MYELOID LEUKAE, PRESENT	AGREE	NOT REVIEWED	
1307		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1308		0	LIVER - NORMAL	MISSING SLIDE	NOT REVIEWED	
1309		1	LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1310		0	LIVER - ANGIECTASIS, PRESENT	MISSING SLIDE	NOT REVIEWED	
1311		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	



# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1311	Cont'd	1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1312		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
1313		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1314		1	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
1315		2	LIVER - NORMAL	AGREE	NOT REVIEWED	
1316		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1317		1	LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
				LIVER - ANGIECTASIS (-)	NOT REVIEWED	
1318		1	LIVER - NORMAL	AGREE	NOT REVIEWED	
1319		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 3F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 6

**Chemical #**  
**CAS #**  
**Dosage** 0 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1319		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
1320		1	LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
59		2	LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	LIVER: HEPATOCLR ADEN (-)	
			LIVER - HEPATOCLR CARC, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-) [PWG]	AGREE WITH BOTH	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
60		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
61		1	LIVER - CHOLANGIOMA, PRESENT	LIVER, BILE DUCT - CYST (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
62		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
62		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
67		1	LIVER - CHOLANGIOMA, PRESENT	LIVER - HEPATOCHOLANGIOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
68		1	LIVER - BLRY DCT FIBRO, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	LIVER - ANGIOMATOUS HYPERPLASIA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
69		1	LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
69	Cont'd	1		LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
70		1	LIVER - ANGIOMATOUS HY, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
71		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCLR CARC (-)	
				LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BILIARY DUCTS HYPERPLASIA (-)[PWG]	LIVER: CHOLANGIOMA (-)	
76		2				

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
76		2	LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
77		2	LIVER - CHOLANGIOCARC, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
78		3	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
79		3	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
79	Cont'd	3		LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
80		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
81		1	LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
82		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No. Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
82		1	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
85		4	LIVER - HAEMANGIOSARCO, PRESENT	LIVER - NECROSIS (-)[PWG]	NOT PRESENT IN SECTION (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HISTIO SARC, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	
86		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
87		3	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	



# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
87	Cont'd	3	LIVER - HEPATOCLR ADEN, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
91		2	LIVER - ANGIOMATOUS HY, PRESENT	AGREE[PWG]	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	NOT REVIEWED	
92		2	LIVER - CHOLANGIOMA, PRESENT	LIVER, BILE DUCT - CYST (-)[PWG]	LIVER: HEPATOCLR ADEN (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
93		3	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			<Inserted Finding>		LIVER: HEPATOCLR ADEN (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
97		2				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 2F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 4

**Chemical #**  
**CAS #**  
**Dosage** 6,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
97		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
98		6	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	LIVER: HEPATOCLR CARC (-)	
			LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			<Inserted Finding>		LIVER: EOSIN FOCUS (-)	
99		2	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 2

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
13		1	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
14		1	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
15		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	AGREE WITH REVIEWING PATHOLOGIST	
21		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
			<Inserted Finding>		LIVER: HEPATOCLR ADEN (-)	
22		2	LIVER - CHOLANGIOCARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HAEMANGIOSARCO, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
23		3				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 2

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
23		3	LIVER - CHOLANGIOCARC, PRESENT	AGREE[PWG]	LIVER: HEPATOCLR CARC (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - NEOPLASTIC NOD, PRESENT	LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	LIVER: HEMANGIOMA (-)	
			<Inserted Finding>		LIVER: EOSIN FOCUS (-)	
31		1	LIVER - HEPATOCLR ADEN, PRESENT	AGREE[PWG]	LIVER: HEPATOCLR CARC (-)	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
32		4	LIVER - CHOLANGIOMA, PRESENT	NOT PRESENT IN SECTION (-)	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	LIVER - HEPATOCHOLANGIOCARCINOMA (-)	AGREE WITH BOTH	
39		1	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	

# SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 2

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
39	Cont'd	1	LIVER - NODULAR HYPERP, PRESENT	LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
40		1	LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
41		1	LIVER - HEPATOCLR ADEN, PRESENT	LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
42		2	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
45		1				

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 2

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
45		1	LIVER - ANGIO HYP ATYP, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
46		1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	LIVER: HEPATOCLR CARC (-)	
			<Inserted Finding>		LIVER: BASOPH FOCUS (-)	
47		1	LIVER - ANGIO HYP ATYP, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
				LIVER - HEPATOCELLULAR ADENOMA (-)[PWG]	NOT PRESENT IN SECTION (-)	
48		1	LIVER - NECROSIS, PRESENT	AGREE[PWG]	NOT PRESENT IN SECTION (-)	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 2

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
48	Cont'd	1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: EOSIN FOCUS (-)	
				LIVER - HEPATOCELLULAR CARCINOMA (-)[PWG]	LIVER: HEPATOCLR ADEN (-)	
49		5	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCHOLCARC (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			<Inserted Finding>		LIVER: CHOLANGIOCARC (-)	
			LIVER - HEPATOCLR CARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			<Inserted Finding>		LIVER: EOSIN FOCUS (-)	
50		0	LIVER - MISSING	MISSING SLIDE	NOT REVIEWED	
55		4	LIVER - CHOLANGIOMA, PRESENT	AGREE[PWG]	LIVER: HEPATOCLR ADEN (-)	
			LIVER - HAEMANGIOSARCO, PRESENT	New Finding - After[PWG] {AGREE}	AGREE WITH STUDY PATHOLOGIST	

## SLIDE REVIEW WORKSHEET

**Study Title** VINYL CHLORIDE  
**Laboratory** CRC  
**Group** 1F  
**Sex & Species** FEMALE SPRAGUE DAWLEY RAT

TMT 2

**Chemical #**  
**CAS #**  
**Dosage** 10,000 PPM  
**Sacrifice**

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
55	Cont'd	4	LIVER - HEPATOCLR CARC, PRESENT	New Finding - After[PWG] {AGREE}	AGREE WITH STUDY PATHOLOGIST	
				LIVER - BASOPHILIC FOCUS (-)[PWG]	LIVER: HEPATOCHOLCARC (-)	
56		2	LIVER - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NODULAR HYPERP, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
57		1	LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT REVIEWED	





Experimental Pathology Laboratories, Inc.

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## **APPENDIX C**

### **PWG PARTICIPANTS CURRICULA VITAE**

**Charles B. Clifford, D.V.M., Ph.D.**

email charles.clifford@crl.com

**Present Position**

Director, Pathology and Technical Services, Charles River

**Education**

1974	B.S. (Zoology)	Michigan State University
1977	D.V.M.	Michigan State University
1981-1983	Pathology Residency	Walter Reed Army Institute of Research
1988	Ph.D. (Pathology) minors in Immunology and Cell Biology	Cornell University

**Professional and Scientific Societies**

American College of Veterinary Pathologists (Diplomate, by examination)	1983 - present
Society of Toxicologic Pathologists (Full Member)	1989 - present
American Veterinary Medical Association	1981 - present
American Association of Laboratory Animal Science	1992 - present

## Experience

- 1977-1978 Veterinary Officer, Veterinary Detachment, Bayonne, NJ. Supervised approximately 30 civilian and military personnel who inspected most subsistence shipped to the U.S. military in Europe. Conducted sanitary inspection of 5 commissaries and over 80 civilian food processors and suppliers in New York City, Long Island and northern New Jersey. Responsible for zoonosis control at 4 Army posts.
- 1978 Assistant Officer-in-Charge, Team D, 106th Medical Detachment, Pusan, Republic of Korea. Supervised inspection of all subsistence shipped to the U.S. Army in Korea, and managed the only two military veterinary clinics within a 90 mile radius.
- 1978-1979 Officer-in-Charge, Team A, 106th Medical Detachment, Oujongbu, Republic of Korea. Supervised all food inspection for U.S. troops stationed north of Seoul, including along the DMZ, public health consultation for the 2nd Infantry Division. Also was Assistant Chief and Surgeon for the U.S. Army veterinary clinic in Seoul.
- 1979-1980 Course Director, US Army Animal Care Specialist School, Washington, DC, the only school in the U.S. Army to train Animal Health Technicians. Was responsible for course content and administration, counseling and supervision of 5 faculty members, and 120 students per year. Taught courses in pathology, anesthesia, radiology, and the Cardiovascular, Respiratory and Gastrointestinal System.
- 1980-1983 Pathology Resident, Division of Pathology, Walter Reed Army Institute of Research. Provided collaborative histopathology support to the institute, including studies of renal toxicity, pulmonary trauma and toxicity using rodent, lagomorph, canine, and primate models. Served as diagnostic pathologist for the Institute's rodent and primate colonies. Completed all requirements for the board examination of the American College of Veterinary Pathologists.
- 1982-1984 Assistant Senior Army Social Aide to the President of the United States for White House functions, such as receptions and State dinners.
- 1983-1984 Staff Pathologist, Division of Pathology, Walter Reed Army Institute of Research. Developed a rat model and conducted independent research on pathogenesis and healing of pulmonary lesions due to concussive pressure waves. Collaborated in studies of hemorrhagic shock, military systems hazards assessment, and toxicopathology of anti-schistosomal drugs. Assisted in training of 3 pathology residents per year in preparation of the veterinary pathology board examination.
- 1984-1987 Research Assistant (doctoral student), Cornell University. Conducted original research on the ontogeny of neutrophil function and the inflammatory response, comparing fetuses, neonates, and adults. Designed a novel model of *in utero* pulmonary inflammation in the sheep, permitting repetitive blood sampling and bronchoalveolar lavage. Initiated and developed a histopathology training series for

3 veterinary pathology residents from non-English speaking countries. Each resident then successfully completed the veterinary pathology board examination. Completed all requirements for Doctor of Philosophy degree.

1987-1991 Research Pathologist and Assistant Chief of Pathology, Letterman Army Institute of Research. Supervised the Institute's postmortem and clinical pathology laboratories. Conducted original research in distribution and toxicity of purified modified hemoglobin solutions. Collaborated with other scientists in model design and pathology support of Good Laboratory Practices Act-compliant toxicity studies (principal pathologist), pathogenesis of neurovascular trauma, hemorrhagic shock and perfusion injury, wound healing, and pre-clinical testing of candidate resuscitative fluids. Served on a rotating duty as diagnostic pathologist for animal postmortem examinations. Member of the Institute's Animal Care and Use Committee.

1991-2001 Staff Officer, US Army Medical Research and Materiel Command. Two weeks annual duty as a senior staff member in office with budget and program oversight of all Army biomedical research concerning biological and chemical agents, >\$100 million/annum. Duties included technical review of research proposals, analysis and synopsis of diverse research projects for senior pentagon management. Retired as Colonel.

1991-1993 Senior Pathologist, Charles River Laboratories. Oversee all aspects of pathology support of the world's largest supplier of laboratory animals, with approximately \$600 million in annual sales and production facilities in the U.S. and more than 10 other countries. Collaborate in the definition of new animal models, including genetically engineered animals. Supervise extramural development of new diagnostic technologies. Design and conduct pathology service protocols in support of biotechnology and pharmaceutical customers. Address and resolve customer concerns regarding unexpected research findings or other pathology-related issues. Key professional for CRL swine xenotransplantation efforts.

1993-present Director, Pathology and Technical Services. (*additional duties to above*) Supervise two other pathologists and the Charles River Technical Assistance Department, which provides information to customers concerning normative data, test procedures, husbandry, health, and all other matters relating to laboratory animals. Oversee corporate toxicology consultant, preparation of technical and reference papers on Historical Control Data..

2001-2003 (additional duties) Direct responsibility for Contract Research Services department, approximately \$2 million annual revenue. Specialty areas include oncology, vaccine testing, novel imaging studies.

## Licensure

Michigan, #5124, 1977 to present.

## Inventions

Hairless Immunodeficient Mouse Model (U.S. application no. 12/047,948)

## PUBLICATIONS

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2. Zwahlen, R.D., Slauson, D.O., Neilsen, N.R., and **Clifford, C.B.**, Increased Adhesiveness of Complement-Stimulated Calf Neutrophils and Its Pharmacologic Inhibition. *Journal of Leukocyte Biology*, 41:465-473, 1987.
3. Boswell, G.D., Brooks, D.E., Murray, A.J., Doye, A.A., Disselhorst, D.J. Chin, C.L., and **Clifford, C.B.**, Exogenous Methemoglobin as a Cyanide Antidote in Rats. *Pharmaceutical Research*, 5:749-752, 1988.
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8. Yuan, X-Q, Wade C.E., and **Clifford, C.B.**, Traumatic Brain Injury Suppresses Spontaneous Hemodynamic Recover from Hemorrhagic Shock in Rats, *J. Neurosurg.* 75:408-414, 1991.

9. Yuan, X-Q, Wade C.E., and **Clifford, C.B.**, Immediate hypertensive response to fluid percussion brain injury may be related to intracerebral hemorrhage and hypothalamic damage. *J.Neurotrauma*, 8:219-228, 1991.
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12. Runyon, D., Bruttig, S, Dubick, M., **Clifford, C.**, Kramer, G., Resuscitation from hypovolemia in swine with intraosseous infusion of a saturated salt-dextran solution, *Journal of Trauma* 36:11-19, 1994.
13. **Clifford, C.B.**, Walton, B.J., Reed, T.H., Coyle, M.B., White, W.J., and Amyx, H.L., Hyperkeratosis in nude mice caused by a coryneform bacterium: Microbiology, transmission, clinical signs, and pathology, *Laboratory Animal Science*, 45:131-139, 1995.
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16. Vargas, K.J., Stephens, C., **Clifford, C.B.**, Gray, K.N., and Price, R.E. Dystrophic cardiac calcinosis in C3H/HeN mice. *Laboratory Animal Science*, 46:572-575, 1996.
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2. Frost, D.F., Omaye, S.T., Zaucha, G.M., **Clifford, C.B.**, Wheeler, C.R., Schuschereba, S.T., and Korte, D.W., Twenty-eight Day Subcutaneous Subchronic Toxicity Study of Physostigmine Salicylate in Rats. Institute Report #317, Letterman Army Institute of Research, U.S. Army, November 1988.
3. Frost, D.M., Zaucha, G.M., Omaye, S.T., **Clifford, C.B.**, and Korte, D.W., Acute Intravenous Toxicity of Hypertonic Saline/Dextran 70 and its Constituents in Beagle Dogs. Institute Report #392, June 1989.
4. Zaucha, G.M., Frost, D.F., Omaye, S.T., **Clifford, C.B.**, and Korte, D.W., Fourteen-Day Subacute Intravenous Toxicity Study of Hypertonic Saline/Dextran 70 and its Constituents in Beagle Dogs. Institute Report #404, Letterman Army Institute of Research, November 1989.
5. Magnuson, D.K., Zaucha, G.M., **Clifford, C.B.**, and Korte, D.W., Primary Dermal Irritation of Physostigmine Salicylate, Physostigmine Free-Base, and Pyridostigmine Bromide in New Zealand White Rabbits. Institute Report #438, Letterman Army Institute of Research, January 1990.
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7. Morgan, E.W., Zaucha, G.M., Waring, P.P., LeTellier, Y., Seewald, J.B., **Clifford, C.B.**, and Korte, D.W., Ninety Day Subchronic Oral Toxicity Study of Pyridostigmine Bromide in Rats. Institute Report #435, Letterman Army Institute of Research, May 1990.
8. Morgan, E.W., Zaucha, G.M., Waring, P.P., LeTellier, Y., Seewald, J.B., **Clifford, C.B.**, and Korte, D.W., One Hundred Eighty Day Subchronic Oral Toxicity Study of Pyridostigmine Bromide in Rats. Institute Report #441, Letterman Army Institute of Research, June 1990.



## ABSTRACTS

1. Slauson, D.O., Skrabalak, D.S., Zwahlen, R.D., Neilsen, N.R. and **Clifford, C.B.**, Equine Neutrophil Aggregation and Adhesiveness Responses to C5a and AGEPC. Joint Conference of the International Leukocyte Culture conference and the Reticuloendothelial Society, 1985.
2. Zwahlen, R.D., Slauson, D.O., Neilsen, N.R., and **Clifford, C.B.**, Adhesiveness Responses of Neonatal Neutrophils to Zymosan-Activated Plasma. Joint Conference of the International Leukocyte Culture Conference and the Reticuloendothelia Society, 1985.
3. **Clifford, C.B.**, Slauson, D.O., Zwahlen, R.D., Schlafer, D.H., and Neilsen, N.R., Superoxide Anion Generation by Bovine Neutrophils: A Comparison of Fetal, Neonatal, and Adult Cells. American College of Veterinary Pathologists Annual Meeting, December, 1985.
4. Zwahlen, R.D., Slauson, D.O., Neilsen, N.R., and **Clifford, C.B.**, Adhesiveness of C5a-Treated Bovine Neonatal Neutrophils: Influence of Anti-Inflammatory Agents. American College of Veterinary Pathologists Annual Meeting, December 1985.
5. Slauson, D.O., Zwahlen, R.D., Neilsen, N.R., and **Clifford, C.B.**, Aggregation and Adhesiveness Responses of Equine Neutrophils to C5a and Platelet Activating Factor. American College of Veterinary Pathologists Annual Meeting, December 1985.
6. Slauson, D.O., Zwahlen, R.D., Neilsen, N.R., **Clifford, C.B.**, Bochsler, P.N., and Enright, F.M., Pharmacologic Inhibition of C5a-induced Increased Adhesiveness of Newborn and Adult Neutrophils by Steroidal and Non-Steroidal Anti-Inflammatory Drugs. American College of Veterinary Pathologists Annual Meeting, December 1986.
7. Miller, R.E., Lightner, L., **Clifford, C.B.**, Reid, W.A., Jones, D., and Witter, K.R., The Efficacy of Topically Applied Niclosamide at Preventing Schistosomiasis mansoni in Rhesus Monkeys. American Society of Tropical Medicine and Health Annual Meeting, 1988.
8. Loveday, J.A., Gonzaludo, G.A., Sondeen, J.L., Rodkey, W.G., **Clifford, C.B.**, Deshon, G.E., Wade, C.E., Surgical Preparation for the Study of Renal Function in Conscious Swine. Presented at American Association for Laboratory Animal Science Annual Meeting, 1989.
9. **Clifford, C.B.**, Wessels, D.W., and Smith, C.D., Morphologic Effects of HBXLA99 in Rats, Biomaterials, Art. Cells, Art. Organs, 17:680, 1989.
10. Schuschereba, S.T., **Clifford, C.B.**, and Vargas, J.A., Effects of Hypervolemic Infusion of Cross-Linked Hemoglobin (DBBF-Hb) on the Rat Retina, Biomaterials, Art. Cells, Art Organs, 17:698, 1989.

11. Korte, D.W., Frost, D.F., Zaucha, G.M., Waring, P.P., **Clifford, C.B.**, and Wheeler, C.R., 28-day Toxicity in Beagle Dogs of Physostigmine Salicylate Administered via Subcutaneously Implanted Alzet Osmotic Minipumps, *Proc. West. Pharmacol. Soc.*, 32:159, 1989.
12. Dubick, M.A., Runyon, D.E., **Clifford, C.B.**, and Kramer, G.C., Comparison of Intraosseous with IV Infusions of Hypertonic Saline Dextran-70, *Ann. Emerg. Med.*, 20:480, 1991.
13. Runyon, D.E., **Clifford, C.B.**, Bruttig, S.P., Wade, C.E., Dubick, M.A., and Kramer, G.C., Resuscitation of Hypovolemia Using Intraosseous Infusion of a Small Volume of 25% NaCl/24% Dextran-70, *Ann. Emerg. Med.*, 20:480, 1991.
14. Bowman, P.D., **Clifford, C.B.**, McFaul, S.J., Tacha, D., and Johnson, T.W., Distribution of Purified Hemoglobin in Mouse Tissue as a Function of Time after Administration: An Immunocytochemical Study. *FASEB*, 1991.
15. **Clifford, C.B.**, Gianni, F.J., and White, W.J., *Pneumocystis carinii* and modern methods of rodent breeding and husbandry. Joint meeting of Am Soc Parasitologists and Soc Protozoologists, 1996.
16. Henderson, K.S., **Clifford, C.B.**, and Dionne, J.A., Comparison of the polymerase chain reaction with histological technique for detection of *Pneumocystis carinii*. Joint meeting of Am Soc Parasitologists and Soc Protozoologists, 1996.
17. Kim, N.M., Bailey, L., Olson, T., **Clifford, C.B.**, Benso, F.J., Sgrulloni, S.J., Duenas, E., Cleland, J.L., Putney, S.D., and Riley, M.G.I., Immunogenicity evaluation of ProLease® hGH: A sustained release formulation. Society of Toxicology, 1997.
18. Albers, T.M. and **Clifford, C.B.** Eosinophilic granulomatous pneumonia: A strain-related lesion of high prevalence in the Brown Norway rat, *Contemporary Topics*, 39(4):61-62, 2000
19. Albers, T. M. and **Clifford, C. B.** Transmission of rat respiratory virus in a rat colony: Gross and histopathological progression of lesions. *Contemp Top.Lab Anim Sci* 42[4], 73-74. 2003.

Curriculum Vitae  
**Dr. Sabine FRANCKE-CARROLL**  
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

DHHS/CFSAN/FDA/ OFAS/ Senior Science and Policy Staff /Pathology  
5100 Paint Branch Parkway HFS-205  
College Park MD 20740  
(301) 436-1308

**EDUCATION:**

Ph.D., The Ohio State University, Columbus, OH, USA  
Applied Veterinary Pathology Residency, The Ohio State University, Columbus, OH, USA  
Dr. Vet. Med., Justus-Liebig University, Giessen, Germany  
D.V.M., Justus-Liebig University, Giessen, Germany

**PROFESSIONAL ORGANIZATIONS AND MEMBERSHIPS:**

Recognized Fellow of the International Academy of Toxicologic Pathology (IATP; 2010 - present)  
European Society of Toxicologic Pathology (ESTP; 2009 – present)  
US Society of Toxicologic Pathology (STP; 1998 - present)  
American College of Toxicology (ACT; 1999 - present)  
Association of Government Toxicologists (AGT; 2000- present) – President Elect (2009-11)  
Charles Louis Davis D.V.M. Foundation for the Advancement of Veterinary and Comparative Pathology (2000 – present)

United States and Canadian Academy of Pathology, Inc. (USCAP 2000-2010)  
American Association for the Advancement of Science (AAAS 1992-2010)  
National Society for Histotechnology (NSH 2004-2009)

**PROFESSIONAL EXPERIENCE:**

**CURRENT DUTIES:**

Expert Toxicologic Veterinary Regulatory Review Pathologist, Senior Science and Policy Staff / Pathology  
Department of Health and Human Services / FDA / CFSAN / OFAS /College Park, MD.

4/10 – present

The incumbent in the Office of Food Additive Safety (OFAS) in CFSAN is recognized by FDA as subject matter expert for Toxicologic Veterinary Regulatory Review Pathology (Veterinary Officer / Pathologist) and serves as an authoritative expert in her field, conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs independent histo-pathological slide evaluations and serves as authoritative expert in regulatory toxicologic veterinary pathology on Center-, Inter Agency-, and national / international professional committees and provides a regulatory perspective when serving on Pathology Working Groups (PWGs) convened to resolve complex pathology issues.

Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Senior Toxicologic Veterinary Pathologist, Senior Science and Policy Staff / Pathology  
Department of Health and Human Services / FDA / CFSAN / OFAS /College Park, MD.

2/2007- 3/10. The incumbent serves in the Office of Food Additive Safety (OFAS) in CFSAN as Toxicologic Veterinary Pathologist (Veterinary Officer / Pathologist) conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs a wide range of administrative functions pertaining to the budget process, property management and pathology contract management.  
Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Acting Branch Chief, Pathology Branch  
Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

1/2005-2/2007 Center-wide Reorganization. The incumbent is an experienced regulatory reviewer and applies in-depth professional knowledge and skills as Veterinary Medical Officer / Pathologist conducting independent safety evaluations of pathology data from regulatory petitions for the Division of General Scientific Support (DGSS).

The incumbent manages independently the Pathology Branch and the associated histopathology laboratory, performing a wide range of administrative functions pertaining to daily operations (such as the budget process, property management and contract management). The Pathology Branch and the Pathology Laboratory provide a full range of pathology support functions

**Dr. Sabine FRANCKE-CARROLL**

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

**PROFESSIONAL EXPERIENCE (contd.):**

for requesting Offices/researchers such as pathology protocol design, monitoring animal-study in-life-phases, performing necropsies, guiding the tissue processing, evaluating histological glass slides and reporting of pathology data. The incumbent instructs and trains laboratory associated personnel and adjunct students from the University of Maryland. The incumbent is solely responsible for the development and application of all immuno-histopathological services provided by the Pathology Laboratory.

Supervisor: Prem Dua, D.V.M., Ph.D., (Director, DGSS, OSAS, CFSAN/FDA)

Senior Staff Toxicologic Pathologist

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

01/2002-12/2004. The incumbent assists the Director of the Division of General Scientific Support (DGSS) with regulatory (food petition) reviews. To do this the incumbent applies knowledge of FDA laws/regulations and extensive experience in pathology data analysis. The incumbent is further involved in administrative matters pertaining to the operation of the Pathology Branch, e.g. the zero based budgeting process. The incumbent's significant research experience involves her extensively as Co-principal investigator in several research projects with Center and/or adjunct scientists from the University of Maryland (UMD). The incumbent serves as student mentor and instructor to laboratory personnel and UMD/JIFSAN students, and promotes the development of immuno-histopathological services provided by the Pathology Laboratory.

Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Staff Toxicologic Pathologist

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

01/2001 – 12/2002. The incumbent provides histo-pathological analysis and support to requesting researchers associated with Governmental Offices (e.g. OARSA) and/or joint facilities such as the University of Maryland (under the umbrella of the Joint Institute for Food Safety and Applied Nutrition (JFSAN)). The incumbent participates as Immuno-pathologist and/or as Co-principal-investigator in protocol design, monitors animal-study in-life-phases, performs necropsies, guides the tissue processing, evaluates histological slides and conducts the final pathology-relevant reporting of assigned animal research studies. The incumbent initiates the development of immuno-histopathological services provided by the Pathology Laboratory.

Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Toxicologic Pathologist, Novartis Pharmaceuticals Inc. East Hanover, NJ.

11/98 – 11/2000. The incumbent generates and evaluates pathology data of assigned acute, subacute and chronic preclinical drug-safety studies which also entailed partial, direct/indirect supervision of technical personnel assigned to these studies. The incumbent is assigned to projects with standard design and/or those requiring an appropriate level of interpretive experience and knowledge. A current knowledge of recent advances and new equipment/procedures is important to achieve optimum results. At the conclusion of each study, the incumbent participates in the data review/analyses to determine target organ toxicity. The incumbent participates in the study design and in the evaluation and implementation of new procedures to improve preclinical drug-safety operations. The incumbent is a member of scientific boards, project teams, and advisory committees and performs other duties as assigned by upper management.

Supervisor: Dr. Pritam Sahota, D.V.M, Ph.D.

Veterinary Research Pathologist, Pathology Associates International (PAI), Immunology and Molecular Pathology Division  
Frederick, MD 21701

09/1996 – 98. The incumbent evaluates designs and interprets studies assessing the cross-reactivity characteristics of monoclonal antibodies in human and animal tissues (in vivo/in vitro exposure), the localization of monoclonal antibodies by means of immuno-labeling techniques and conducts development and application of molecular and cellular histopathologic technology to characterize and resolve mechanistic problems associated with biopharmaceutical product development.

Supervisor: Bill Hall, V.M.D., Ph.D.

**Dr. Sabine FRANCKE-CARROLL**

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

**PROFESSIONAL EXPERIENCE (contd.):**

Graduate Research Associate (Ph.D. / Veterinary Pathologist), The Ohio State University, Department of Veterinary Biosciences, Columbus, Ohio

1992-1996 Research conducted evaluates anti-retroviral drug-effects (mainly AZT) on cellular immune responses and immune-cell precursor frequencies. Effector-cell frequency analysis, by limiting dilution analysis (LDA), allows not only qualitative assessment but also quantitation of the effects noted. Two animal models, an outbred feline model for retroviral infection and an inbred mouse model for allograft rejection are utilized in these studies. Research activities: Histopathology, immunology, retro-virology, in-vivo and in-vitro drug testing, immunohistochemistry, vaccine development, cell culture and molecular biology.

Thesis advisor: Lawrence E. Mathes, Ph.D., Professor.

Graduate Teaching Associate and Resident (Veterinary Pathologist / Ph.D.)

1990-1992 (continued services during Ph.D training until 1996) The Ohio State University  
Department of Veterinary Biosciences  
Columbus, Ohio

Graduate Assistant (Dr.med.Vet.)

1988-1990 Justus-Liebig University  
Giessen, Germany

Research performed to obtain a "Dr. Vet. Med." degree centers on the immunohistologic characterization of the cellular immune response to bacterial infection with *Coxiella burnetii* in a murine model. Results illustrated that cellular mechanisms are crucially involved in the pathogenesis of chronic infection with *C. burnetii*.

Thesis advisor: Dr. Wolfgang Baumgaertner, D.V.M., Ph.D., Professor.

Graduation from Veterinary School (DVM)

1988 Justus-Liebig University  
Giessen, Germany

**LEADERSHIP EXPERIENCE:**

- Elected board member to IATP 2011: Vice president 2011-13; President 2013-15
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA recognized (Agency Peer Review) Expert for Toxicologic Veterinary Regulatory Review Pathology (April 2011)
- President Elect of the Association of Government Toxicologists (AGT term 2010-2011)
- Councilor to the Board of the Association of Government Toxicologists (AGT), 2006 & 2008
- CFSAN Immunotox Redbook working group: chair
- STP SRPC Regulatory Liaison since 2005 till present
  - Hepatic Enzyme Induction working group liaison since 2007/ chair – Dec 2008-10
  - Historical Control Data working group SRPC liaison, 2006-2009
- Pathology Laboratory Chief, and Acting Pathology Branch Chief; providing training, instructions and guidance to Laboratory Technicians and visiting scientists from UMD, regarding duties and functions of the Pathology Branch and its Laboratory.
- Mentor to JIFSAN students; Mentor to UMD and Pathology Laboratory students.
- Histopathology mentor and instructor for Laboratory Biologist: training included pathology terminology, histology, histopathology, tissue trimming, tissue processing, preparation of paraffin blocks, microtoming, H&E staining of routine slides, Immunohistochemical staining, archiving, laboratory administrative work and reagent ordering.

**SERVICES AND RESPONSIBILITIES:**

- Regulatory liaison to the Scientific Regulatory and Policy Committee (SRPC) of the Society of Toxicologic Pathology (STP) since 2005
  - SRPC liaison to the Historical Control Data working group; 2006 -09 - Best Practice manuscript published TP 2009; 37(5) 679-93.
  - SRPC liaison to the Hepatic Enzyme Induction Risk Assessment (HEI- RA) working group since 2007; chair since Dec. 2008 – 2010.
  - SRPC liaison to the Joint Regulatory Affairs Committee (JRAC) between STP and the American College of Veterinary Pathology (ACVP); since 2006 - 2009.
  - Invited Member of the STP Regulatory Forum editorial group for the Journal of Toxicologic Pathology since 2007 – ongoing.
- CFSAN Immunotox Redbook committee since 2006
  - Chair: Dec 07 – ongoing.
- Association of Government Toxicologists (AGT)
  - Board member councilor 2005-07; elected for–second term 2008; President elect 2009-10; President 2010-11; Past President 2011-12 – 3 year leadership commitment - ongoing.
- Acting Chief of the Pathology Branch and Laboratory / DGSS (1/2005- until CFSAN reorganization 2/2007).
- CFSAN Cancer Assessment Committee (CAC) Member – Pathologist – since 2004.
- CFSAN Pathology Services and Archiving Contract Project Officer since 2006 – recertified as COTR July 31, 2009.
- Property Management Officer 2005-07.
- CFSAN Science Council Committee Member since 2004.
  - SC Scientific Dissent Resolution policy draft subcommittee 2007-09.
  - SC membership charter following the CFSAN 2007 reorganization subcommittee Scientific Achievement Award-subcommittee (2004, '05, '06, '07, '08).
  - Manuscript clearance subcommittee 2004.
- CFSAN Toxicology Redbook Committee Member since 2003.
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) steering Committee Member 2002-'07. And JIFSAN Grant – Pathology Support Collaborator to the University of Maryland (UMD), Department of Food Science.

**AWARDS / Professional Recognitions**

- Recognized FDA Expert for Toxicologic Veterinary Regulatory Review Pathology through Agency peer review March 2010.
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA / CFSAN Outstanding Customer Service Award, Office of Food Additive Safety for *pathology support to CDRH on the histopathological evaluation of mouse tissues for the distribution of nano-material*, June 2008.
- FDA and Center-level Crosscutting Award that includes CFSAN Employees, FDA Melamine Award, Adulterated protein investigations, analysis, planning, scientific review and emergency response team for *exemplary performance to protect the public health from adulterated protein through actions of investigations, sample analyses, method development, assignment, planning, emergency response, scientific review and risk assessment*, June 2008.
- FDA / CFSAN Honor Award: Aspartame Carcinogenicity Review Team, Office of Food Additive Safety for *exceptional performance in evaluating the results of a number of carcinogenicity studies on aspartame, including the high-profile European Ramazzini Foundation study*, June 2008.
- FDA Outstanding Service Award for *outstanding performance while participating on an expert pathology review panel in response to an Inter-Center pathology support request from CDER* June 2007.
- FDA Outstanding Service Award for *outstanding performance in the regulatory review of pathology issues and in providing critical pathology support to the Office of Food Additive Safety* June 2006.
- FDA Outstanding Service Award for *sustained superior performance in evaluating and resolving complex regulatory pathology review issues as well as supporting collaborating scientists* June 2005.
- FDA Outstanding Service Award for *sustained superior performance in the evaluation of substantial and voluminous regulatory and experimental pathology data* June 2004.
- Team Award as member of the OARSA Food Allergenicity Team for *outstanding team effort in successfully completing pilot studies to evaluate a unique animal model for the study of human food allergenicity* June 2003.
- FDA Outstanding Service Award for *sustained superior performance in the Pathology Branch instituting a food-allergy rat model, leveraging with the UMD and establishing a IH laboratory* June 2003

Curriculum Vitae  
**Dr. Sabine FRANCKE-CARROLL**  
Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

- Quality Performance Award for *developing methods to quantify "altered crypt foci" in the colon of rats* July 2002
- Quality Performance Award for *Pathology support services with the University of Maryland (UMD)* June 2002

**PUBLICATIONS AND PRESENTATIONS:**

**Technical Reports:** lists on       - regulatory review projects (upon request)  
  - regulatory research projects (upon request).

**Poster / Journal presentations and Talks:**

Boorman G., Wolf D., Francke-Carroll S., and Maronpot R. Guest Editorial: Pathology Peer Review. Tox Path 38:1009-1010, 2010.

Botts S., Ennulat D., Francke-Carroll S., Graham M., Maronpot R., and Mohutsky M. Introduction to Hepatic Drug Metabolizing Enzyme induction in Drug Safety Evaluation Studies. Tox Path 38: 796-798, 2010.

Mohutsky M., Romeike A., Meador V., Lee W., Fowler J. and Francke-Carroll S. (Chair) Introduction to Hepatic Drug Metabolizing Enzyme induction in Drug Safety Evaluation Studies. Tox Path 38: 799-809, 2010.

Griffis L., Twerdok L.E., Francke-Carroll S., Biles R., Schroeder R., Bolte H., Hall W., Faust H. and Rojko J. Comparative 90-day dietary study of paraffin wax in Fischer-344 and Sprague-Dawley rats. Food and Chemical Toxicology: 2010, 48: 363-372.

Patri A., Umbreit T., Zeng J., Nagashima K., Goering P., Francke-Carroll S., Golden E., Weaver J., Miller T., Sadrieh N., McNeil S., and Stratmeyer M. Energy dispersive X-ray analysis of titanium dioxide nanoparticle distribution after intravenous and subcutaneous injection in mice. Journal of Applied Toxicology 2009, 29: 667-672.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin, Peddada, S., R., Pletcher J., Rinke M., Schmidt S., Taylor I. and Wolf D. Potential for a Global Historical Control Database for Proliferative Rodent Lesions. Tox Path 2009; 37(5) 677-8.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin, Peddada, S., R., Pletcher J., Rinke M., Schmidt S., Taylor I. and Wolf D. Regulatory Forum: Best Practices for Use of Historical Control Data of Proliferative Rodent Lesions. Tox Path 2009; 37(5) 679-93.

Kerlin R., Hutto D., Silverman L., Francke-Carroll S., Vahle J. Regulatory forum for Toxicologic Pathology: an update. Toxicologic Pathology 2008; 36(5):760.

Austin C., Umbreit T., Brown K., Barber D., Dair B., Francke-Carroll S., Feswick A., Saint-Louis M., Hikawa H., and Goering P. Distribution of iv-injected silver nanoparticles in pregnant mice and developing embryos. Poster presentation at the Society of Toxicology's 48<sup>th</sup> annual meeting held in Baltimore MD, March 15-19, 2009.

Invited Talk: Francke-Carroll S., Society of Toxicologic Pathology (STP), 27<sup>th</sup> annual meeting: As Module of the Effective Communication for the Toxicologic Pathologist - Career Development Courses: "Communicating Pathology Information Effectively to Regulatory Agencies". San Francisco, CA June 20-26, 2008.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin R., Pletcher J., Rinke M., Schmidt S., Taylor I., Wolf D. STP Working Group on Historical Control Data of Proliferative Rodent Lesions. Presented at the 26<sup>th</sup> annual meeting of the Society of Toxicologic Pathology (STP) in San Juan, Rio Mar, Puerto Rico, June 2007.

Umbreit T.H., Goering P.L., Miller T.J., Weaver J.L., Francke-Carroll S., Sadrieh N., Kauffman J., Guthrie J., Robertson J., Stratmeyer M.E.: *Toxicity and Tissue Distribution of Titanium Dioxide (TiO<sub>2</sub>) Nanoparticles in subcutaneous and intravenously injected mice over 6 months* Poster presentation at the Society of Toxicology's 47<sup>th</sup> annual meeting held in Seattle, WA, March 21-26, 2008.

Curriculum Vitae  
**Dr. Sabine FRANCKE-CARROLL**

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

**PUBLICATIONS AND PRESENTATIONS (contd.)**

Daly K., Tracy A., Francke-Carroll S., Wang T., Malik M. and Magnuson B.A. Enhanced estrogenic responses and sensitivity to azoxymethane following dietary soy isoflavone supplementation in older female rats. *Food Chem Toxicol* 2007 Apr; 45 (4):628-37.

Umbreit T., Goering P., Francke-Carroll S., Patri A., McNeil S., Weaver J., Miller T., Sadrieh N., and Stratmeyer M. *Energy dispersive X-ray analysis of titanium dioxide nanoparticle distribution in mice*. Poster presentation at the Society of Toxicology's 46<sup>th</sup> annual meeting held in Charlotte, NC March 25-29, 2007.

Yoon DM, Hawkins EC, Francke-Carroll S, Fisher JP. Effect of construct properties on encapsulated chondrocyte expression of insulin-like growth factor-1. *Biomaterials* 2007 Jan 28 (2); 299-306.

Morton D, Kemp RK, Francke-Carroll S, Jensen K, McCartney J, Monticello TM, Perry R, Pulido O, Roome N, Schafer K, Sellers R, Snyder PW. Best practice for reporting pathology interpretations within GLP toxicology studies. *Tox Path* 2006; 34 (6); 806-9.

Su Y., Yu T., Lala G., Francke-Carroll S., and Magnuson B.A. Protection of side effects of 5-fluorouracil by anthocyanin-rich extracts. International Research Conference on Food and Nutrition and Cancer, Washington DC, July 2005. Published in *J. Nutr.* 135.12S:3054.

Ferri, M, Francke-Carroll S. and Magnuson B.A. JIFSAN Student project: Development of immuno-histochemical staining techniques for PCNA and APOPTOSIS tissue markers on rat tissues in the CFSAN Pathology Laboratory. Poster presentation at the 11<sup>th</sup> Annual FDA Science Forum, 2005, Washington Convention Center, Washington DC.

Hinton D.M., Lorenzo M., Harper S.B. and Francke-Carroll S., (2004). USFDA, CFSAN, Laurel, MD. Progress in the evaluation of an in-bred rat strain ("asthmatic rat") for predicting the allergic potential of food and other Proteins. Seminar presented at OFAS/CFSAN/USFDA Vermont Ave May 6, 2004.

Hinton D.M., Lorenzo M.E., Harper S.B., Francke-Carroll S., O'Neill R.K., Chirtel S.J., Calvo M.S. An In-Bred Rat Strain (the FDA "Asthmatic Rat") for Predicting the Allergic Potential of Proteins and for Evaluating the Efficacy of Drugs and Dietary Supplements in Respiratory (Asthmatic) and Cardiovascular Studies Poster presentation (Board Number B-08) at the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Magnuson B., Daly K., Malik M., Wang T., Francke-Carroll S. Enhanced Sensitivity of Female Rats to Azoxymethane following Dietary Soy Isoflavone Supplementation. Poster presentation at the 10<sup>th</sup> Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age-related liver pathology increases azoxymethane toxicity in F344 female rats in an aging study on colon cancer chemoprevention with dietary soy. Website publication (Board Number D-PO-01) for the 10<sup>th</sup> Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age related liver pathology increases Azoxymethane toxicity in F344 female rats in an aging study on colon cancer and nutrition. Poster presentation # 500 at the Society of Toxicology's 43<sup>rd</sup> annual meeting held in Baltimore, MD, March 21-26, 2004.

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Curriculum Vitae  
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**PUBLICATIONS AND PRESENTATIONS (contd.)**

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Francke S., Orosz C.G., Hsu J, and Mathes L.E.: Immunomodulatory Effect of Zidovudine (ZDV) on Cytotoxic T Lymphocytes Previously Exposed to ZDV. Antimicrob Agents Chemother Sept; 46 (9): 2865-71, 2002.

Francke-Carroll S., Montgomery J.E., Hines F.A., and Magnuson B.A.: The Effect of a Dietary Curcumin Supplement on the Development of Histopathological Age-associated Changes in Male Azoxymethane-Treated F344 Rats. Presented at the twenty-first Annual Symposium of the Society of Toxicologic Pathology, Denver, CO, June. 2-6, 2002.

Francke S., Orosz C.G., Hayes K.A. and Mathes L.E.: Effect of Zidovudine on the primary cytolytic T-lymphocyte response and T-cell effector function. Antimicrob Agents Chemother Jul; 44(7): 1900-5, 2000.

Hayes K.A., Phipps A, Francke S. and Mathes L.E.: Antiviral therapy reduces viral burden but does not prevent thymic involution in young cats infected with feline immunodeficiency virus. Antimicrob Agents Chemother Sep; 44(9): 2399-2405, 2000.

Mathes L.E., Hayes K.A., Francke S. and Phipps A.: Comparison of pathogenesis of the Mount Airy strain of feline immunodeficiency virus (FIV-MD) in pediatric and adult cats. Presented at the Third International Feline Retrovirus Research Symposium, Ft. Collins, CO, March 6-9, 1998.

Francke S. Evaluation of the Immunomodulatory effects of the anti-retroviral drug Zidovudine (AZT). Presented in partial fulfillment of the requirements for the degree Doctor of Philosophy in the Graduate School of The Ohio State University. The Ohio State University, Columbus, OH, USA, 1996.

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Hayes K.A., Wilkinson J.G., Frick R., Francke S. and Mathes L.E.: Early suppression of viremia by ZDV does not alter the spread of feline immunodeficiency virus infection in cats. J Acq Immune Syndr & Hum Retrovir 9:114-22, 1995.

Francke S. Histological and immunohistological evaluation of the spleen in Balb/cJ (H-2<sup>d</sup>) mice following infection with *Coxiella burnetii*. (Histologische und immunhistologische Untersuchung der Milz von Balb/cJ (H-2<sup>d</sup>)-Mäusen nach Infektion mit *Coxiella burnetii*): Inaugural - Dissertation, Veterinary Medicine, Justus-Liebig-University, Giessen, Germany, 1991.

## **PETER GREAVES MBChB FRCPath**

*Dr Greaves is a medical graduate trained in laboratory medicine, specialising in human and experimental histopathology and toxicology. He has over twenty-five years experience in human and experimental pathology as well as toxicology, pre-clinical drug safety evaluation and drug development. He advises both pharmaceutical companies and government in these areas.*

### **PROFESSIONAL HISTORY:**

#### **CONSULTING PATHOLOGIST**

**March 2005 – present:**

*Advises on preclinical drug safety evaluation and toxicological pathology. Engaged in research in toxicological pathology, carcinogenesis and cancer chemoprevention. Member of the Committee on Carcinogenicity, United Kingdom*

#### **MEDICAL RESEARCH COUNCIL TOXICOLOGY UNIT, LEICESTER**

**March 2000 – February 2005: Senior Research Scientist & Head of Pathology.**

*Responsibility for the histopathological study of disease models and adverse hepatic effects of drugs in obesity in combination with genetic analysis, laser capture dissection microscopy, in situ hybridisation and immunocytochemistry.*

#### **ASTRAZENECA (FORMERLY ZENECA, ICI PHARMACEUTICALS), ALDERLEY PARK, CHESHIRE**

**March 1990 - February 2000: Head of Safety of Medicines Group**

*Responsibility for all preclinical safety studies and kinetics and metabolism work with approximately 300 staff in the UK and US in support of the discovery and development of novel drugs for all of ex-ZENECA Pharmaceuticals.*

#### **ZENECA (FORMERLY ICI) PHARMACEUTICALS, ALDERLEY PARK, CHESHIRE**

**January 1989 - February 1990: Head of Pathology**

*Responsibility for a group of 80 staff conducting histopathological evaluation of toxicity studies.*

#### **PARKE-DAVIS RESEARCH INSTITUTE, MISSISSAUGA, ONTARIO, CANADA**

**January 1987 - December 1988: Director of Research Institute**

*Responsibility for the Sheridan Park Research Laboratory (60 staff) undertaking preclinical safety studies for Parke-Davis Research centred at Ann Arbor, Michigan.*

#### **WELLCOME RESEARCH LABORATORIES, BECKENHAM, KENT, ENGLAND**

**January 1985 - December 1986: Head of Toxicology and Metabolism**

*Responsibility for drug safety evaluation, preclinical drug kinetics and radiochemistry at the Beckenham site (50 staff), in collaboration with Experimental Pathology and Toxicology at Research Triangle Park site.*

#### **CENTRE DE RECHERCHE, LABORATOIRES PFIZER, AMBOISE, FRANCE**

**September 1981 - December 1984: Director of Pathology**

**April 1979 - August 1981 - Pathologist**

**WESTMINSTER HOSPITAL MEDICAL SCHOOL & ST STEPHEN'S HOSPITAL,  
LONDON**

September 1976 - March 1979 - Senior Registrar in Histopathology

February 1975 - February 1976 - Registrar in Histopathology

**MEDIZINISCHE HOCHSCHULE, HANNOVER, GERMANY.**

February 1976 - September 1976 - Assistant in Pathology

**NEWCASTLE GENERAL HOSPITAL, NEWCASTLE-UPON-TYNE**

September 1972 - February 1975 - Senior House Officer in Pathology

**GRAVESEND HOSPITAL, KENT**

October 1972 - May 1972 - House Physician

**CHICHESTER HOSPITAL, WEST SUSSEX**

February 1971 - August 1971 - House Surgeon

**EDUCATION AND DEGREES:**

- \* MBChB University of Birmingham, England, 1969
- \* MRCPPath in human histopathology, Royal College of Pathologists, London, 1977
- \* FRCPath in histopathology & toxicology, Royal College of Pathologists, London, 1989
- \* GMC Registration in Morbid Anatomy and Histopathology under the European Specialist Medical Qualifications order 1995 (number 1491454)
- \* Medical Defence Union membership (membership number 095078D)

**OTHER ACTIVITIES:**

- \* Member of the *Committee on Carcinogenicity*, United Kingdom 2008-present
- \* Member of *International Life Sciences Institute (ILSI) – Europe* project on data selection for modelling of substances that are genotoxic and carcinogenic 2009-2011
- \* Chairman of *International Harmonization of Nomenclature and Diagnostic Criteria* committee for rodent soft tissue pathology 2009-present
- \* Member of the *Veterinary Products Committee* of the United Kingdom 2003-2007
- \* Member of the editorial board for *Toxicologic Pathology* 2002-2006
- \* Member of the editorial for board for *Experimental & Toxicologic Pathology* 2000-2007.
- \* Chairman of *Zeneca Leisure* 1996-1999: This group managed all the company leisure activities, clubs and leisure facilities, turnover £1 million per annum
- \* Member of Personnel steering group for *Zeneca R&D* in the UK 1996-1999
- \* Member of Health & Safety Steering Committee for the Alderley Park R&D site 1996-1999
- \* Biological Safety Officer, MRC Toxicology Unit 2000-2003

**Date:** 21 July 2010

## PUBLICATIONS:

### Books:

Greaves P. and Faccini J.M. (1992): Rat Histopathology: A Glossary for Use in Toxicity and Carcinogenicity Studies, 2<sup>nd</sup> edition. Elsevier, Amsterdam.

Greaves P. (2007): Histopathology of Preclinical Toxicity Studies: Interpretation and Relevance in Drug Safety Evaluation. Elsevier, Amsterdam. 3<sup>rd</sup> edition.

### Main scientific papers:

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Greaves P. and Faccini J.M. (1981): Fibrous histiocytic neoplasms spontaneously arising in rats. *Br.J.Cancer*, **43**, 402-411.

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Green, A.R. Styles, J.A., Parrott, E.L., Gray, D., Edwards, R.E., Smith, A.G., Gant, T.W. Greaves, P., Al-Azzawi, F. and White, I.N.H (2005): Neonatal tamoxifen treatment of mice leads to adenomyosis but not uterine cancer. *Exptl. Toxicol. Pathol.* **56**, 255-263.

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- Greaves, P. (2008): Preclinical testing. In: *Encyclopedia of Cancer*, 2<sup>nd</sup> edition, (ed. M. Schwab), Springer-Verlag, Heidelberg.
- Verschoye, R.D., Greaves, P., Patel, K., Marsden, D., Brown, K., Steward, W.P. and Gescher, A.J. (2008): Evaluation of the cancer chemopreventive efficacy of silibinin in genetic mouse models of prostate and intestinal carcinogenesis: Relationship with silibinin levels. *European Journal of Cancer*, **21**, 898-906.
- Teichert, F., Verschoye, R.D., Greaves, P., Edwards, R.E., Teahan, O., Jones, D., Wilson, I.D., Farmer, P.B., Steward, W.P., Gant, T.W. and Gescher, A.J. Keun, H.C (2008): Metabolic profiling of transgenic adenocarcinoma of mouse



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Teichert, F., Verschoyle, R.D., Greaves, P., Thorpe, J.F., Mellon, J.K., Steward, W.P., Farmer, P.B., Gescher, A.J. and Singh, R. (2009): Determination of 8-oxo-2-deoxyguanosine and creatinine in murine and human urine by liquid chromatography-tandem mass spectrometry: application to chemoprevention studies. *Rapid Communications in Mass Spectrometry*, **23**, 258-266.

Greaves P. (2009): Pathological techniques in toxicology. In: General and Applied Toxicology, pp 691-706, B. Ballantyre T. Marrs and T. Syversen, (Eds), 3<sup>rd</sup> Edition. John Wiley and Sons Ltd., Chichester.

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Bruner R., Greaves, P., Hard G.C., Regan, K., Ward, J.M., David, R.M. Histopathologic changes in the kidneys of male F344 rats from a 2-year inhalation carcinogenicity study of tetrahydrofuran. A pathology working group review and re-evaluation. *Regulatory Toxicology and Pharmacology*. **In press**. Online publication: 31 May 2010

Teichert, F., Verschoyle, R.D., Greaves, P., Jones, D.J.L., Wilson, I.D., Farmer, P.B. Steward, W.P., Gescher, A.J., and Keun H.C. Plasma metabolic profiling reveals age-dependency of systemic effects of green tea polyphenols in mice with and without prostate cancer. *Molecular BioSystems*. **In press**



**JERRY F. HARDISTY**  
**CHIEF EXECUTIVE OFFICER/SENIOR PATHOLOGIST**

**EDUCATION:**

Iowa State University, Pre-Veterinary, 1965-1967  
Iowa State University, D.V.M., 1971  
Certified by the American College of Veterinary Pathologists, 1976  
Adjunct Associate Professor at the School of Veterinary Medicine,  
NC State University, 1983

**PRESENT POSITION AND EXPERIENCE:**

2010 - Present. Chief Executive Officer/Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the overall implementation of the strategic goals and objectives of EPL. Provide leadership toward the company's philosophy, mission, strategy, and goals and objectives. Direct the company's business development and marketing efforts. Serve as the Principal Investigator as a Study Pathologist, Peer Review Pathologist and Chairperson for Pathology Working Groups and Scientific Advisory Panels.

1998 - 2010. President and Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of contract research pathology laboratories in Virginia and North Carolina. The company serves both government and university research and the safety assessment programs of the pharmaceutical, chemical, and cosmetic industries.

1994 - 1998. Vice President, Operations and Pathologist, Experimental Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of pathology research laboratories in North Carolina and Virginia.

1978 - 1994. Director and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the project management, direction and technical supervision of the North Carolina branch of EPL. Responsible for the microscopic evaluation of toxicological studies. Responsible for the National Toxicology Program's Pathology Quality Assessment Program and Operations of the NTP Archives.

1976 - 1978. Pathologist/Project Manager, Experimental Pathology Laboratories, Inc., Herndon, Virginia

Responsible for the management of EPL's Carcinogenesis Support Laboratory. Project Manager of a program to provide Tracor Jitco with Quality Assurance in the NCI Carcinogenesis Testing Program. Technical supervision of a program to provide pathology support services to the Carcinogenesis Program of the National Cancer Institute. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies.



**JERRY F. HARDISTY, DVM, DACVP**

**PRESENT POSITION AND EXPERIENCE – Continued**

1972-1976      Research Pathologist, Veterinary Pathology Branch, Biomedical  
Laboratory, Edgewood Arsenal, Maryland

Dr. Hardisty was a preceptee in the U.S. Army preceptorship program in Veterinary Pathology. During this time he performed gross and microscopic diagnoses of spontaneous disease and changes produced by experimental procedures in laboratory animals. He prepared reports describing and interpreting these experimental results.

During this time he was principal investigator for the reproductive, mutagenic, teratogenic studies performed at the laboratory. This work consisted of revising previous experimental protocols and designing new experimental protocols to be utilized at the laboratory. The experimental design employed required the gross examination of pregnant female rats and fetuses for evidence of fetal toxicity and teratogenesis. He trained biological technicians to perform timed matings in rats, examine serially sectioned fetuses for malformations, and to examine fetal skeletons for prenatal abnormalities.

1971-1972      Attending Veterinarian, Division of BioSensor Research,  
Walter Reed Army Institute of Research

Dr. Hardisty studied the radiographic and morphologic lesions of several musculoskeletal diseases of the German Shepherd Dog. In association with Dr. Wayne Riser, he investigated the pathogenesis and possible genetic relationship of canine hip dysplasia, eosinophilic panosteitis and ununited anconeal processes in an attempt to reduce their incidence through a selective breeding program.

**PROFESSIONAL MEMBERSHIPS:**

Diplomate, American College of Veterinary Pathologists

ACVP Subspecialty in Toxicologic Pathology

American College of Toxicology

Society of Toxicology

Society of Toxicologic Pathologists

British Society of Toxicologic Pathologists

International Academy of Toxicologic Pathology

American Veterinary Medical Association

North Carolina Society of Toxicology

Charles Louis Davis, D.V.M. Foundation

The Society of Phi Zeta

The Society of Gamma Sigma Delta

The Fraternity of Alpha Zeta

The Fraternity of Omega Tau Sigma

American Association for the Advancement of Science

Standardized System of Nomenclature and Diagnostic Criteria (SSNDC), The



**JERRY F. HARDISTY, DVM, DACVP**

**PROFESSIONAL ACTIVITIES – Continued**

Society of Toxicologic Pathologists, 1987-1995.

Executive Committee, The Society of Toxicologic Pathologists, 1994- 1998.

Executive Committee Chairman, The Society of Toxicologic Pathologists, 1997-1998.

Joint Committee for STPs/ILSI on International Standardization of  
Nomenclature and Diagnostic Criteria for Toxicologic Pathology, 1994-1995,  
Co-Chairman 1995-Present.

President-Elect, The Society of Toxicologic Pathologists, 1999-2000.

President, The Society of Toxicologic Pathologists, 2000-2001.

Past President, The Society of Toxicologic Pathologists, 2001-2002.

Long Range Planning Committee, American College of Toxicology, 2002.

North American Director, International Academy of Toxicologic Pathology, 2002.

FDA Clinical Pharmacology Subcommittee of the Advisory Committee for  
Pharmaceutical Sciences, FDA Center for Drug Evaluation and Research, 2003.

**EDITORIAL REVIEW BOARD:**

International Agency for Research on Cancer (WHO), Classification of Rodent Tumors, Part II,  
The Mouse, 1995-2001.

Editorial Review Board for *Fundamental and Applied Toxicology*, Society of Toxicology Board of  
Publications, 1996-1998.

Editorial Review Board for *Toxicological Sciences*, Society of Toxicology Board of Publications,  
1998-2004.

Editorial Review Board for *Experimental and Toxicologic Pathology*, 2000.

Editorial Board of *Toxicologic Pathology*, 2006-2008.

**PUBLICATIONS AND PAPERS:**

Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid, Hormone 1-84 in a 2-  
Year Study in Fischer 344 Rats. The Society of Toxicologic Pathology

Factors predisposing to urolithiasis in feedlot cattle. Hardisty JF and Dillman RC. The Iowa  
State University Veterinarian, Iowa State University, Ames, Iowa, 33(2), 77-81, 1971.

Reduction of frequency of hip dysplasia in military dogs. Riser WH, Hardisty JF and Castleberry  
MW. In Proceedings, Canine Hip Dysplasia Symposium and Workshop, OFA, Columbia, MO.  
1972.

Genetic influence of the male on the incidence of canine hip dysplasia. Hardisty JF, Scalera  
SE., Castleberry MW and Riser WH. In Proceedings, Canine Hip Dysplasia Symposium and  
Workshop, OFA, Columbia, MO. 1972.



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

Evaluation of the effects of chemical compounds on the reproductive system of rats. Hardisty JF. Presented at the Biomedical Laboratory Review and Analysis, April 1975.

Reproductive studies with quint essence compounds. Hardisty JF, Presented at the Biomedical Laboratory Review and Analysis of Quint Essence, January 1976.

Effects of KZ/IP mixture on the reproductive system. Hardisty JF and Pellerin RJ. Edgewood Arsenal Technical Report, 1976.

Reproductive studies with diisopropylmethylphosphate in rats. Hardisty JF, Pellerin RJ, Biskup RF and Manthei JH. Edgewood Arsenal Technical Report ARCSL TR 77037, May 1977.

Quality assurance in pathology. Hardisty JF, Ward JM and Griesemer RA. NCI-NCTR Pathology Workshop, Bethesda, MD, June 1978.

Mononuclear cell leukemia in Fischer 344 rats. Hardisty JF. NCI-NCTR Pathology Workshop, Bethesda, MD, June 1978.

Quality assurance for pathology in rodent carcinogenesis tests. Ward JM, Goodman DG, Griesemer RA, Hardisty JF, Schueler RL, Squire RA and Strandberg JD. Journal of Environmental Pathology and Toxicology, 2, 371-378, Nov.-Dec. 1978.

Neoplasms and pigmentation of the thyroid gland in F-344 rats exposed to 2,4-diaminoanisole sulfate, a hair dye component. Ward JM, Stinson, SF, Hardisty JF, Cockrell BY and Hayden DW. Journal of the National Cancer Institute, Vol. 62, No. 4, 1979. Apr;62(4) 1067-73

Renal carcinogenic and nephrotoxic effects of the flame retardant TRIS[(2,3-dibromopropyl) phosphate] in F-344 rats and B6C3F1 mice. Reznik G, Ward JM, Hardisty JF and Russfield A. Journal of the National Cancer Institute, Vol. 63, No. 1, July 1979.

Correlation between gross observations of tumors and neoplasms diagnosed microscopically in carcinogenesis bioassays in rats. Kulwich BA, Hardisty JF, Gilmore CE and Ward JM. Journal of Environmental Pathology and Toxicology, 3, 281-287, December 1979.

Evaluation of procedures suggested for reducing the pathology workload in a carcinogenesis testing program. Hardisty JF, Ward JM, Douglas JF and Fears TR. Journal of Environmental Pathology and Toxicology, 3, 167-176, December 1979.

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Presented for the conference to re-evaluate the Toxicology of Vinyl Chloride Monomer, Polyvinyl Chloride and Structural Analogues on March 20-21, 1980, at the National Institute of Health, Bethesda, MD.

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Environmental Health Perspectives, 41, 63-72, October 1981.

Carcinogenesis bioassay of 2,6-Xylidine in rats. Hardisty JF, Montgomery CA and Kornreich M. The Toxicologist, Vol 3, No. 1, March 1983.

Chronic toxicity and oncogenicity bioassay of inhaled toluene in Fischer 344 rats. Gibson JE and Hardisty JF. Fundamental and Applied Toxicology, 3: 315-319, 1983.



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

Quality assurance in pathology for rodent carcinogenicity tests, by GA Boorman, CA Montgomery, JF Hardisty, SL Eustis, MJ Wolfe and EE McConnell. In: Handbook of Carcinogen Testing, (H Millman and E Weisberger, eds), pp. 345-357. New Jersey: Noyes Publications, 1985.

Systemic effects following inhalation of fog oil obscurant. Hardisty JF, Stead AG, Grose EC and Selgrade MJ. Presented at the North Carolina Chapter of the Society of Toxicology Meeting on February 2, 1985.

Factors influencing laboratory animal spontaneous tumor profiles. Hardisty JF. Toxicologic Pathology, 13, 91-104, 1985.

Pulmonary and hepatic health effects of inhalation of petroleum smoke. Grose EC, Stevens MA, Illing JW, Jaskot RH, Hardisty JF and Stead A. The Toxicologist, Vol 6, No. 1, March 1986.

National Toxicology Program Pathology Quality Assurance Procedures, by J.F. Hardisty and GA Boorman. In: Managing Conduct and Data Quality of Toxicology Studies, (BK Hoover, JK Baldwin and AF Uelner. NIEHS/NTP – CE Whitmire, CL Davies and DW Bristol, eds), pp 263-269. New Jersey: Princeton Scientific Publishing Co. Inc., 1986.

Pulmonary Effects Due to Short Term Exposure to Oil Fog. Selgrade MJK, Hatch GE, Grose EC, Illing JW, Stead AG, Miller FJ, Graham JA, Stevens MA and Hardisty JF. Journal of Toxicological Environmental Health. 1987 21(1-2):173-85.

Arsine: Toxicity data from acute and subchronic inhalation exposures. MP Moorman, CR Moorman, JF Hardisty, SL Eustis, RE Morrissey, HR Sanders and BA Fowler. The Toxicologist, Vol 7, No. 1, February 1987.

Chronic toxicity and oncogenicity study of 2,6 diethylaniline. TG Pullin, RW Naismith, JF Hardisty, EB Whorton Jr. and GL Ter Haar. The Toxicologist, Vol 8, No. 1, February 1988.

Peripheral nerve sheath tumors, rat, by D.M. Walker, V.E. Walker, J.F. Hardisty, KT Morgan and JA Swenberg. In: ILSI Monographs on Pathology laboratory animals, nervous system, Vol 6, (TC Jones, U Mohr and RD Hunt, eds), New York, Springer-Verlag, 1988.

Pulmonary Effects Due to Subchronic Exposure to Oil Fog. Selgrade MK, Hatch GE, Grose EC, Stead AG, Miller FJ, Graham JA, Stevens MA, Hardisty JF. Toxicology and Industrial Health, Vol 6, No. 1, 1990 Jan, 6(1):123-43.

Thyroid gland, by JF Hardisty and GA Boorman. In: Pathology of the F344 Rat, (G Boorman, S Eustis, C Montgomery, M Elwell and W MacKenzie, eds), San Diego, Academic Press, 1990.

Oral cavity (pharynx, tongue, gingival teeth), esophagus and stomach, by HR Brown, JF Hardisty and SL Eustis. In: Pathology of the F344 Rat, (G Boorman, S Eustis, C Montgomery, M Elwell and W MacKenzie, eds), San Diego, Academic Press, 1990.

Toxicological pathology: a critical stage in study interpretation, by JF Hardisty and SL Eustis. In: Progress in Toxicology, (D Clayson, I Munro, P Shubik and J Swenberg, eds), Amsterdam, Elsevier, 1990.



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

Tumors of the skin in the HRA/Skh mouse after treatment with 8-methoxypsoralen and UVA radiation. JK Dunnick, PD Forbes, SL Eustis and JF Hardisty. Fund. & Appl. Tox., Vol 16, 92-102, 1991.

Proliferative lesions of the mouse lung: Progression studies in Strain A mice. JF Foley, MW Anderson, GD Stoner, BW Gaul, JF Hardisty and RR Maronpot. Experimental Lung Research, Vol.17, 157-168, 1991.

Lesions of the rodent liver. Hardisty JF. Presented at the Dose Response Relationships for Hepatocarcinogenesis in Medaka Exposed to Waterborne N-Nitrosodietylamine. Workshop on December 15, 1993.

Procedures for peer review in toxicologic pathology. Hardisty JF. Presented at The Society of Toxicologic Pathologist 13<sup>th</sup> International Symposium on June 5-9, 1994.

Necropsy and histology in toxicologic pathology. Hardisty JF. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, July 27, 1994.

A comparison of liver tumor diagnoses from seven PCB studies in rats. Moore John A, Hardisty Jerry F, Banas Deborah A and Smith, Mary Alice. Regulatory Toxicology and Pharmacology, Vol 20, 362-370, 1994.

Neoplastic lesions of questionable significance. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 3, 1994.

Use of nasal diagrams to record nasal lesions. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 4, 1994.

Morphologic assessment of pathologic changes in the rat larynx. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 4, 1994.

Pathology peer review and PWG. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 23, 1995

Peer review in toxicology pathology. Ward JM, Hardisty JF, Hailey JR and Street CS. Toxicologic Pathology ISSN:0192-6233, Vol. 23, No. 2, 1995

Computerized pathology data – summary vs. individual. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 24, 1995.

An evaluation of changes in the olfactory epithelium and liver peroxisome proliferation in mice after inhalation exposure to methylethylketoxime. Newton PE, Bolte HF, Lake

BG, Derelanko M, Rinehart WE and Hardisty JF. The Toxicologist, Vol 30, No. 1, Part 2, March 1996.

Peer review of histopathology data. Hardisty JF. Presented at the American College of Toxicology 17th Annual Meeting in King of Prussia, PA on November 11, 1996.

Pathology peer review in assessing carcinogenicity studies. Hardisty JF. Presented at the American College of Veterinary Pathologists' Thirty- First Annual Meeting in Seattle, Washington on December 5, 1996.



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

Value of the mouse carcinogenicity bioassay (Summary). Hardisty JF. Toxicologic Pathology ISSN:0192-6233, Vol. 24, No. 6, 1996, pp. 720-721.

Interaction of consultants, contract laboratories and industry-Panel Discussion with HE Black, AM Dahlem, JF Hardisty, TG Terrell. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 19, 1997.

Controversial issues in anatomic pathology. JF Hardisty. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 20, 1997.

Phenolphthalein induces thymic lymphomas accompanied by loss of the p53 wild type allele in heterozygous p53-deficient (+) mice. Dunnick JK, Hardisty JF, Herbert RA, Seely JC, Furedi-Machacek EM, Foley JF, Lacks GD, Stasiewicz S and French JE. Toxicologic Pathology, Vol. 25, No. 6., 533-540, 1997.

Diagnostic dilemmas in toxicologic pathology. Hardisty Jerry. Presented at The 22nd Annual CL Davis DVM Foundation Continuing Education Symposium at North Carolina State University, College of Veterinary Medicine in Raleigh, North Carolina on June 14-18, 1998.

Thyroid and parathyroid glands, by JF Hardisty and GA Boorman. In: Pathology of the Mouse, (RR Maronpot, GA Boorman and BW Gaul, eds), Vienna, IL, Cache River Press, 1999.

Rodent Leydig Cell Tumorigenesis: A Review of the Physiology, Pathology, Mechanisms, and Relevance to Humans. Jon C Cook, Gary R Klinefelter, Jerry F Hardisty, Richard M Sharpe and Paul MD Foster. Critical Reviews in Toxicology 1999 March;29/169-261.

The nomenclature of cell death: recommendations of an ad hoc committee of Society of Toxicologic Pathologists. Levin S, Bucci TJ, Cohen SM, Fix AS, Hardisty JF, Legrand EK, Maronpot RR and Trump BF. Toxicologic Pathology. 1999 Jul-Aug;27(4):484-490.

Controversial issues in anatomic pathology. Hardisty Jerry. Presented as a course entitled *Industrial Toxicology and Pathology* for the American Registry of Pathology at the Ramada Inn in Bethesda, MD on September 28, 1999.

Histopathology of nasal olfactory mucosa from selected inhalation toxicity studies conducted with volatile chemicals. Hardisty JF, Garman RH, Harkema JR, Lomax LG and Morgan KT. Toxicologic Pathology, Vol.27, No. 6, pp. 618-627, 1999.

Pathology Working Groups: Current Concepts. Hardisty JF. Presented at the 16<sup>th</sup> Annual Meeting of the Society of Quality Assurance in Montreal, Canada on October 9-13, 2000.

Blind Pathology – When and When Not. Hardisty JF. Presented at the 51<sup>st</sup> Annual Toxicology Roundtable Program in Asheville, NC on October 15-18, 2000.

Short-Term, Subchronic, and Chronic Toxicology Studies, by NH Wilson, JF Hardisty and JR Hayes. In: Principles and Methods of Toxicology, 4<sup>th</sup> Edition, (Wallace Hayes, ed), ISBN 1-56032-814-2, 2000.

Methods to identify and characterize developmental neurotoxicity for human health risk assessment. II: neuropathology. Garman RH, Fix AS, Jortner BS, Hardisty JF, Claudio L and Ferenc S. Environmental Health Perspectives, Vol. 109, pp. 93-100, March 2001.





**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

A chronic inhalation toxicity/oncogenicity study of methylethylketoxime in rats and mice. Newton PE, Wooding WL, Bolte HF, Derelanko MJ, Hardisty JF and Rinehart WE. *Inhalation Toxicology*, 13:1093-1116, 2001.

Carcinogenic assessment of premafloxacin in rats and mice. White KA, Daniel EM, Botta JA, Clare LJ, Barnett D, Hildebrandt P, Hardisty JF and Lucas MJ. Presented as a poster for the

Society of Toxicologic Pathology and the International Federation of Societies of Toxicologic Pathologists in Orlando, Florida on June 24-28, 2001.

The Pathologist and Pathology Data. Hardisty JF. Presented at FDA CEDR on May 31, 2001.

Inhalation Toxicology of Octamethylcyclotetrasiloxane (D4) Following a 3-month Nose-Only Exposure in Fischer 344 rats. Burns-Naas LA, Meeks RG, Kolesar GB, Mast RW, Elwell MR, Hardisty JF, Thevenaz P. *International Journal of Toxicology* 2002 Jan-Feb;21(1):39-53.

Quality review procedures necessary for rodent pathology databases and toxicogenomic studies: The National Toxicology Program Experience. Boorman GA, Haseman JK, Waters WD, Hardisty JF and Sills RC. *Toxicologic Pathology*. 30, 88-92, 2002.

Inhalation toxicology of octamethylcyclotetrasiloxane (D<sub>4</sub>) following a 3-month nose-only exposure in Fischer 344 rats. Burns-Naas LA, Meeks RG, Kolesar GB, Mast RW, Elwell MR, Hardisty JF and Thevenaz P. *International Journal of Toxicology*, ISSN 1091-5818, Vol. 21, No. 1, pp 39-53, 2002.

Diagnostic dilemmas in toxicologic pathology. Presented at the 5<sup>th</sup> Industrial Toxicology and Pathology Course and symposium in Chicago, IL on July 9, 2002.

Histologic artifacts & diagnostic dilemmas. Presented at the RTP Rodent Pathology Course, Research Triangle Park, NC on September 8-10, 2002.

Comparative prevalence, multiplicity, and progression of spontaneous and vinyl carbamate-induced liver lesions in five strains of male mice. Takahashi K, Dinse GE, Foley JF and Maronpot RR. *Toxicologic Pathology*, Vol 30, No. 5, pp 599-605, 2002.

Propylene glycol monomethyl ether (PGME): inhalation toxicity and carcinogenicity in Fischer 344 rats and B6C3F<sub>1</sub> mice. *Toxicologic Pathology*, Vol 30, No. 5, pp 570-579, 2002.

An evaluation of changes and recovery in the olfactory epithelium in mice after inhalation exposure to methylethylketoxime. Newton PE, Bolte HF, Derelanko MJ, Hardisty JF and Rinehart WE. *Inhalation Toxicology*, 14:1249-1260, 2002.

The pathologist and pathology data. Hardisty JF. Presented at NIEHS, RTP, NC on February 29, 2002.

The pathologist and pathology data. Hardisty JF. Presented at the SOT Meeting in Nashville, TN on March 2002.

Propylene Glycol Monomethyl Ether (PGME); Inhalation Toxicity and Carcinogenicity in Fischer 344 rats and B6C3F<sub>1</sub> mice. Spencer PJ, Crissman JW, Stott WT, Corley RA, Cieszlak FS, Schumann AM, Hardisty JF. *Toxicological Pathology* 2002 Sep-Oct;30(5):570-9.

Histologic artifacts and diagnostic dilemmas. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

The pathologist and pathology data. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.

The pathologist and pathology data. Hardisty JF. Presented at Health Canada in Ottawa, Canada on December 2, 2002.

Necropsy and histology techniques. Hardisty JF. Presented at FDA on January 9, 2003.

Current approaches to Peer Review and PWG. Hardisty JF. Presented at Battelle in Columbus, OH on June 5, 2003.

Characterization of intrathoracic mesothelioma in Fischer 344/N rats. Willson G, Clayton N, Hardisty J, and Pearse G. Presented as a poster for the Society of Toxicologic Pathology, 22<sup>nd</sup> Annual Meeting In Savannah, Georgia on June 15-19, 2003.

Transplacental carcinogenicity of azidothymidine in B6C3F1 mice and F344 rats. Walker DM, Hardisty JF, Ruecker FA, Funk KA, Wolfe MJ and Walker VE. Abstract No. 548. 2004 *Itinerary Planner*. Baltimore, MD: Society of Toxicology.

Comparison of automated software with conventional histopathology of liver step sections in an NTP Subchronic Bioassay. Willson GA, Joron TA, Lesniak D, Pearse G and Hardisty JF. Presented a poster at the STP Meeting in Salt Lake City, UT, June, 2004.

Automated Pathology Systems – Human Versus Machine Vision. Hardisty JF: Toxicology Roundtable, Augusta, MI. Sept. 2004.

Comparative hepatic toxicity: prechronic/chronic liver toxicity in rodents. Hardisty JF and Brix AE. *Toxicologic Pathology*, 33:35-40, 2005.

ACT/STP Pathology Course for Non-Pathologists. Hardisty JF. Speaker at ACT/STP Meeting, Lincolnshire, IL, May 10-13, 2005.

Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid Hormone 1-84 in a 2-year study in Fischer 344 rats. Jolette J, Wilker CE, Smith SY, Doyle N, Hardisty JF, Metcalfe AJ, Marriott TB, Fox J, Wells DS. *Toxicological Pathology* 006;34(7):929-40.

Optimization in Pathology. Presented at RCC Scientific Workshop Basel on October 19, 2006.

Diagnostic Dilemmas in Toxicologic Pathology, Hardisty JF. Speaker, Presented at the 7th Biennial Industrial Toxicology & Pathology Short Course, Co-sponsored by the Society of Toxicologic Pathology and the University of Illinois College of Veterinary Medicine, July 23–25, 2007.

Histopathology of Hemangiosarcoma in Mice Hamsters and Liposarcomas/Fibrosarcomas in Rats Associated with PPAR Agonists. Hardisty JF, Elwell MR, Ernst H, Greaves P, Kolenda-Roberts H, Malarkey DE, Mann PC, Tellier PA. *Toxicologic Pathology*, 35:928-941, 2007.

General Principles in Necropsy and Histology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

Current Practices in Toxicologic Pathology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

Chronic Progressive Nephropathy and Proliferative Lesions of the Renal Tubule, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

Histopathology of the Urinary Bladders of Cynomolgus Monkeys Treated with PPAR Agonists. Hardisty JF, Anderson DC, Brodie S, Cline JM, Hahn FF, Kolenda-Roberts H, Lele SM, Lowenstine LJ. Toxicological Pathology, 2008;36 769-776.

Ocular Collection Protocol for the Laboratory Rabbit, Dog, and Monkey. Render JA, Dubielzig RR, Dunn DG, Hardisty JF, Moore RR, Sabio DA. Presented as a poster for the 6<sup>th</sup> European Congress of Toxicologic Pathology, Edinburgh, Scotland on September 24 - 26, 2008.

"Larynx Squamous Metaplasia". A Re-consideration of Morphology and Diagnostic Approaches in Rodent Studies and its Relevance for Human Risk Assessment. Kaufmann W, Bader R, Ernst H, Harada T, Hardisty JF, Kittel B, Kölling A, Pino M, Renne R, Rittinghausen S, Schulte A, Wohrmann, T, Rosenbruch M. Presented at The 1st International ESTP Expert Workshop, Ludwigshafen, Germany; Published: Experimental and Toxicologic Pathology, 61 (2009) 591-603

Regulatory Perspective for Pathology Data. Manabe S, Oishi Y, Tamura K, Schorsch F, Weber K, Hardisty JF, Kuranami K. Panel Discussion: Presented at the 25th JSTP Annual Meeting, Hamamatsu, Japan, January 28, 2009. Published: Journal of Toxicologic Pathology 2009; 22: 209-227

Lesions in the Larynx of Wistar KccHan™: WIST Rats. Weber K, Germann PG, Iwata H, Hardisty JF, Kaufmann W, Rosenbruch M. Published: Journal of Toxicologic Pathology 2009; 22: 229-246

Thyroid Dysplasia in Wistar Hannover GALAS Rats. Weber K, Ernst R, Fankhauser H, Hardisty JF, Heider W, Stevens K. Published: Journal of Toxicologic Pathology 2009; 22: 247-254

International Prospective on Peer Review. North American Perspective presented by Hardisty JF. The 2010 Town Hall Meeting at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

Optimal Routine Sampling of the Cynomolgus Monkey Nervous System in Toxicity Studies. Hardisty JF, Moore R. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

Innumohistochemical Study of Brain Tumors in Rats Treated with Acrylonitrile. Kolenda-Roberts H, Hardisty JF. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

A Commentary on the Process of Peer Review and Pathology Data Locking. McKay JS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Manabe S, Schorsch F, Terancishi M, Weber K. Published: Journal of Toxicologic Pathology 2010; 38: 508-510



**JERRY F. HARDISTY, DVM, DACVP**

**PUBLICATIONS AND PAPERS – Continued**

Recommendations for Pathology Peer Review. Morton D, Sellers RS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Irizarry A, McKay JS, Odin M, Teranishi M. Published: Journal of Toxicologic Pathology 2010; 38: 1118-1127

Pathology Working Group Review and Evaluations of Prolifer Lesions of Mammary Gland Tissues in Female Rats Fed Ammonium Perfluorooctanoate (APFO) in the diet for 2 years. Hardisty JF, Willson GA, Brown WR, McConniell EE, Frame SR, Gaylor DW, Kennedy GL, Butenhoff JL. Published: PubMed: US National Library of Medicine / National Institutes of Health. PMID: 20307141 [PubMed – indexed for MEDLINE]. Drug Chem Toxicol. 2010 Apr; 33(2): 101-137.

Industry-Contract Research Organization Pathology Interactions: A Perspective of Contract Research Organizations in Producing the Best Quality Pathology Report. Gosselin SJ, Palate B, Parker GA, Engelhardt JA, Hardisty JF, McDorman KS, Tellier PA, Silverman LR. Published: Journal of Toxicologic Pathology 2011; 000: 1-7.

JERRY F. HARDISTY, D.V.M.  
Chief Executive Officer  
Senior Pathologist

April 15, 2011  
DATE



Experimental Pathology Laboratories, Inc.

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**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P.  
VETERINARY PATHOLOGIST**

**EDUCATION:**

Washington University, St. Louis, Missouri, A.B., English Literature, 1966-1970  
University of Missouri, St. Louis, Missouri, Pre-veterinary Studies, 1972-1974  
University of Missouri, Columbia, Missouri, D.V.M., 1975-1979

**CERTIFICATIONS/LICENSURE:**

Certified by the American College of Veterinary Pathologists, 1984

**PRESENT POSITION AND EXPERIENCE:**

**2007 – Present.      Manager, EPL Northwest, Seattle, WA.**

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

**2002 – 2006.      Manager, EPL Northeast, Galena, MD.**

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

**2000 – 2002.      On-Site Consultant, DuPont Pharmaceuticals Company,  
Wilmington, DE.**

Full-time, on-site consultant to DuPont Pharmaceuticals Company. Provided necropsy supervision and microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies by DuPont Pharmaceuticals Company.



**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED**

**1999 – 2000.                      Senior Projects Manager,** Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies for both commercial clients and the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

**1994 – 1999.                      Director and Pathologist,** Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management, direction and technical supervision of the North Carolina Branch of EPL. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies. Provided support to the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

**1990 – 1994.                      Veterinary Pathologist,** Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Duties included histopathologic interpretation of tissues from various laboratory animals used for toxicology and carcinogenesis studies.

**1989 – 1990.                      Pathologist,** EPL Scientific Limited, Harrogate, England.

**1985 – 1989.                      Veterinary Pathologist,** ICI Pharmaceuticals, Division of ICI Americas, Wilmington, Delaware.

**1982 – 1989.                      Staff Pathologist,** Brandywine Zoo, Wilmington, Delaware.

**1982 – 1985.                      Senior Lecturer,** Department of Pathobiology, University of Pennsylvania School of Veterinary Medicine.

**1979 – 1982.                      Resident in Pathology,** National Zoological Park, Washington, DC.



**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED**

**1974 – 1975.**                      **Food Technologist,** Pet Foods Department, Grocery  
R&D, Ralston Purina Co., St. Louis, MO.

**1970 – 1971.**                      **Secondary School Teacher,** St. Louis, MO.

**PROFESSIONAL MEMBERSHIPS:**

American Veterinary Medical Association  
American College of Veterinary Pathology  
Society of Toxicological Pathology  
British Society of Toxicologic Pathologists  
C.L. Davis Foundation for the Advancement of Veterinary  
Pathology  
North Carolina Society of Toxicology

**SERVICE TO PROFESSIONAL ASSOCIATIONS:**

Chairman, STP Nomenclature Subcommittee on the Mammary Gland

Member, STP Nomenclature Subcommittee on the Respiratory System

Adjunct Associate Professor at the School of Veterinary Medicine, NC State  
University, Department of Microbiology, Pathology and Parasitology

Member, STP Symposium Committee, 1995-1998

Co-Chairman, STP Educational Committee, 1996

Chairman, STP Symposium Committee, 1998

Copy Editor, C.L. Davis Foundation Newsletter, 1998

Member, Advisory Board, C.L. Davis Foundation for the Advancement of  
Veterinary Pathology, 2000-2004

Member, Executive Committee, Society of Toxicologic Pathology, 2000-2004

Chairman, STP Journal Committee, 2005

Chair, Global Editorial Steering Committee, 2006-2008

President-Elect, Society of Toxicologic Pathology, 2008-2009

President, Society of Toxicologic Pathology, 2009-2010

Member, ILSI/HESI Subcommittee on Distinguishing Adverse from Adaptive,  
Non-Functional, and Pharmacologic Changes in Toxicology Studies, 2009-2010

**SERVICE TO EDITORIAL BOARDS OF SCHOLARY JOURNALS:**

Reviewer for Toxicologic Pathology, 1998-2002



**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED**

**PROFESSIONAL DEVELOPMENT/SPECIALIZED TRAINING:**

**Educational Activities/Special Lectures:**

- |           |   |
|-----------|---|
| 1981      | Diseases of zoo mammals and birds. Pathology of Laboratory Animals, Washington, D.C.  |
| 1982      | Pathology of zoo animals. Friends of the National Zoo, Washington, D.C.   |
| 1982      | Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in small animal pathology rotation.  |
| 1982-1985 | Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in large animal pathology rotation.  |
| 1983      | University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals.  |
| 1983-1984 | Philadelphia College of Pharmacy and Science. Principles of Pathology.  |
| 1983-1984 | University of Pennsylvania School of Veterinary Medicine, Course 5001, General Endocrine Pathology.   |
| 1983      | University of Pennsylvania School of Veterinary Medicine, Course 4501, Infectious Diseases of Dogs and Cats, Neuroendocrine Pathology.                        |
| 1984      | University of Pennsylvania School of Veterinary Medicine, Course 5401, Infectious Diseases of Dogs and Cats.  |
| 1984      | University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals, Diseases of Horses.                                    |
| 1985      | University of Pennsylvania School of Veterinary Medicine, Course 5402, Diseases of Horses.  |
| 1996      | School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular. |



**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED**

- 1997 School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.
- 1999 Chemical Industry Institute of Toxicology, Pathology Short Course for Toxicologists. Necropsy and Histology Techniques. Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays.
- 2002 Society of Toxicology, Continuing Education Course: Blood and Lymphoid Tissue: Neoplasia of Blood and Lymphoid Tissue.
- 2003 Society of Toxicology, Continuing Education Course: Integrating Toxicologic Pathology into Compound Evaluation and Risk Assessment II: Diagnostic Drift.
- 2006 International Institute of Biotechnology and Toxicology. Chennai, Tamil Nadu, India: Regulatory Toxicologic Pathology
- 2007 School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine The Use of Genetically-Modified-Mice in Toxicology
- 2008 Beijing Pharma and Biotech Center (BPBC) – Sino American Pharmaceutical Professionals Association (SAPA) Beijing Workshop: Toxicologic Pathology in New Product Development. Fundamentals of General and Toxicologic Pathology and Histopathology of the Respiratory System: Nose, Larynx and Lungs.
- 2010 School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine, The Use of Genetically-Modified-Mice in Toxicology and Trust me, I'm a Pathologist.
- National Institute for the Control of Pharmaceuticals and Biological Products and the Society of Toxicologic Pathology: USA-China Carcinogenicity Studies Workshop. Beijing, China. Reading the Rodent Bioassay: Problems, Pitfalls and Peer Review and Common Background Tumors of Laboratory Rodents.



**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED**

**Seminars and Presentations:**

Canine parvovirus. Johns Hopkins Division of Comparative Medicine, Baltimore, 1980.

Parvo-like enteritis in golden lion tamarins. Primate Pathology Workshop, New Orleans, 1980.

Canine parvovirus in South American canids. American Association of Zoo Veterinarians, Washington, D.C., 1980.

Leiomyomas of the genital tract in large zoo mammals. International Academy of Pathology, Chicago, 1981.

Respiratory distress syndrome in neonatal reindeer (poster). International Academy of Pathology, Chicago, 1981.

Herpesvirus infections in old world primates. Johns Hopkins Division of Comparative Medicine, Baltimore, 1981.

Selected diseases of zoo animals. University of Pennsylvania School of Veterinary Medicine, Philadelphia, 1981.

Tuberculous osteomyelitis in captive marsupials (poster). International Academy of Pathology, Boston, 1982.

Selected diseases of zoo animals. Virginia-Maryland Regional College of Veterinary Medicine, Blacksburg, 1982.

Post mortem examination as a technique in research. Symposium on the effects of oil on birds, Stone Harbour, 1982.

Enzootic nasal tumors in sheep. Pennsylvania Diagnostic Workshop, Harrisburg, 1983.

Gross pathology of zoo animals. Eighth Annual C.L. Davis Conference in Veterinary Pathology, Philadelphia, 1984.

Peer review from the perspective of a consultant pathologist. Society for Quality Assurance Annual Meeting, Phoenix, Arizona, 1995.

Lesions of Dioxin in laboratory animals. Society of Toxicologic Pathologists 15th International Symposium, St. Louis, Missouri, 1996.



**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED**

Use of genetically altered mice in short-term bioassays. The 22nd Annual C.L. Davis DVM Foundation Continuing Education Symposium, North Carolina State University, College of Veterinary Medicine, Raleigh, North Carolina, June 14-18, 1998.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Pathology of Genetically-Engineered Mice, National Institution of Health, Bethesda, Maryland, February 24-25, 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. CL Davis Foundation European Pathology Division Symposium, Nantes, France, July 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Wyeth Ayerst Research, Chazy, NY, November 1999.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 17-19, 2000.

Pathology Peer Review: Current Concepts. Society of Quality Assurance, 16<sup>th</sup> Annual Meeting, Montreal, Canada, October 9-13, 2000.

Background pathology of genetically-engineered mouse lines. American College of Toxicology, 21<sup>st</sup> Annual Meeting, San Diego, CA, November 13, 2000.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models sponsored by the CL Davis Foundation, Houston, TX, February 15-17, 2001.

Pathology of Transgenic Mice. CL Davis Foundation European Division Pathology Symposium (Szent Istvan University, Budapest, Hungary), July 5-7, 2001.

Genetically-engineered mice in toxicology. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 13-16, 2002.

Necropsy and Histology: Current Practices in Pathology. Health Canada, Existing Substances Branch, Ottawa, Canada, March 2002.

Pathology Data and Tox-Path Issues. USFDA, May 20, 2002.